

**Clinical trial results:****A Multicenter, International, Randomized, Double-blind, Alendronate-controlled Study to Determine the Efficacy and Safety of Romosozumab in the Treatment of Postmenopausal Women With Osteoporosis****Summary**

EudraCT number	2011-003142-41
Trial protocol	IT LT FI PL BE CZ ES EE GR DE GB SE AT DK LV NO NL HU IE
Global end of trial date	29 June 2017

**Results information**

Result version number	v1 (current)
This version publication date	15 July 2018
First version publication date	15 July 2018

**Trial information****Trial identification**

Sponsor protocol code	20110142
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**Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01631214
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	29 June 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 June 2017
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective was to assess the effect of romosozumab treatment for 12 months followed by alendronate treatment compared with alendronate treatment alone on the subject incidence of:

- clinical fracture (nonvertebral fracture and clinical vertebral fracture); and
- new vertebral fracture

in postmenopausal women with osteoporosis.

Protection of trial subjects:

This study was conducted in accordance with International Council on Harmonisation (ICH) Good Clinical Practice (GCP) and applicable Food and Drug Administration (FDA) or local regulations/guidelines.

The study protocol, subject information, and informed consent form (ICF) were reviewed and approved by the independent ethics committee (IEC) or institutional review board (IRB) for each study center.

Before any study procedures were performed or any investigational products were administered, the investigator obtained written informed consent from each subject after adequate explanation of the aims, methods, anticipated benefits, and potential hazards of the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 May 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	Slovakia: 16
Country: Number of subjects enrolled	South Africa: 154
Country: Number of subjects enrolled	Spain: 38
Country: Number of subjects enrolled	Sweden: 28
Country: Number of subjects enrolled	Taiwan: 6
Country: Number of subjects enrolled	Turkey: 9
Country: Number of subjects enrolled	United Kingdom: 76
Country: Number of subjects enrolled	United States: 57
Country: Number of subjects enrolled	Argentina: 108
Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Austria: 37
Country: Number of subjects enrolled	Belgium: 29
Country: Number of subjects enrolled	Brazil: 295
Country: Number of subjects enrolled	Bulgaria: 112
Country: Number of subjects enrolled	Canada: 40
Country: Number of subjects enrolled	Chile: 24
Country: Number of subjects enrolled	Colombia: 634
Country: Number of subjects enrolled	Czech Republic: 282
Country: Number of subjects enrolled	Denmark: 73

Country: Number of subjects enrolled	Dominican Republic: 29
Country: Number of subjects enrolled	Estonia: 51
Country: Number of subjects enrolled	Finland: 13
Country: Number of subjects enrolled	France: 41
Country: Number of subjects enrolled	Germany: 38
Country: Number of subjects enrolled	Greece: 33
Country: Number of subjects enrolled	Guatemala: 75
Country: Number of subjects enrolled	Hong Kong: 249
Country: Number of subjects enrolled	Hungary: 142
Country: Number of subjects enrolled	Israel: 7
Country: Number of subjects enrolled	Italy: 76
Country: Number of subjects enrolled	Korea, Republic of: 20
Country: Number of subjects enrolled	Latvia: 43
Country: Number of subjects enrolled	Lithuania: 50
Country: Number of subjects enrolled	Mexico: 117
Country: Number of subjects enrolled	Netherlands: 25
Country: Number of subjects enrolled	New Zealand: 9
Country: Number of subjects enrolled	Norway: 35
Country: Number of subjects enrolled	Peru: 119
Country: Number of subjects enrolled	Poland: 704
Country: Number of subjects enrolled	Romania: 23
Country: Number of subjects enrolled	Russian Federation: 157
Worldwide total number of subjects	4093
EEA total number of subjects	1965

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	479
From 65 to 84 years	3286
85 years and over	328

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 270 centers in 41 countries globally from 04 May 2012 to 29 June 2017.

### Pre-assignment

Screening details:

Participants were randomized in a 1:1 ratio to receive romosozumab or alendronate for 12 months. Randomization was stratified by age (< 75 vs. ≥ 75 years). After completion of the double-blind trial period, all participants received open-label alendronate until the end of the trial, with blinding to the initial treatment assignment maintained.

### 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, Assessor

### Arms

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

Arm description:

Participants received 70 mg alendronate once a week and placebo to romosozumab subcutaneously once a month for the first 12 months. After completion of the 12-month double-blind treatment period participants continued to receive 70 mg alendronate once a week until the end of the study.

Arm type	Active comparator
Investigational medicinal product name	Alendronate
Investigational medicinal product code	
Other name	Fosamax®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Alendronate 70-mg tablet taken once a week

Investigational medicinal product name	Placebo to Romosozumab
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 during the double-blind treatment phase.

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

Participants received 210 romosozumab mg subcutaneously once a month and placebo to alendronate orally once a week for the first 12 months. After completion of the 12-month double-blind treatment period participants received 70 mg alendronate once a week until the end of the study.

Arm type	Experimental
Investigational medicinal product name	Placebo to Alendronate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Matching placebo tablet taken once a week during the double-blind treatment phase.

Investigational medicinal product name	Alendronate
Investigational medicinal product code	
Other name	Fosamax®
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Alendronate 70 mg tablet taken once a week during the open-label treatment phase.

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:

Romosozumab 210 mg administered by subcutaneous injection once a month during the double-blind treatment phase.

<b>Number of subjects in period 1</b>	<b>Alendronate/Alendronate</b>	<b>Romosozumab/Alendronate</b>
Started	2047	2046
Received Double-blind Treatment	2040	2038
Completed Double-blind Period	1823	1831
Completed	1503	1523
Not completed	544	523
Death	113	106
Other	22	19
Requirement for alternative therapy	8	3
Noncompliance	16	15
Administrative decision	1	-
Ineligibility determined	5	2
Adverse event, non-fatal	45	45
Consent withdrawn by subject	276	290
Protocol deviation	4	3
Lost to follow-up	54	40

## Baseline characteristics

### Reporting groups

Reporting group title	Alendronate/Alendronate
Reporting group description:	
Participants received 70 mg alendronate once a week and placebo to romosozumab subcutaneously once a month for the first 12 months. After completion of the 12-month double-blind treatment period participants continued to receive 70 mg alendronate once a week until the end of the study.	
Reporting group title	Romosozumab/Alendronate
Reporting group description:	
Participants received 210 romosozumab mg subcutaneously once a month and placebo to alendronate orally once a week for the first 12 months. After completion of the 12-month double-blind treatment period participants received 70 mg alendronate once a week until the end of the study.	

Reporting group values	Alendronate/Alendronate	Romosozumab/Alendronate	Total
Number of subjects	2047	2046	4093
Age Categorical Units: Subjects			
Adults (18-64 years)	240	239	479
From 65-84 years	1642	1644	3286
85 years and over	165	163	328
Age Continuous Units: years			
arithmetic mean	74.2	74.4	-
standard deviation	± 7.5	± 7.5	-
Gender Categorical Units: Subjects			
Female	2047	2046	4093
Male	0	0	0
Race Units: Subjects			
American Indian or Alaska Native	7	5	12
Asian	149	137	286
Black or African American	23	19	42
Native Hawaiian or Other Pacific Islander	2	0	2
White	1415	1447	2862
Multiple	4	2	6
Other	446	436	882
Missing	1	0	1
Ethnicity Units: Subjects			
Hispanic or Latino	662	631	1293
Not Hispanic or Latino	1385	1415	2800
Age Strata per Randomization Units: Subjects			
< 75 years	976	973	1949
≥ 75 years	1071	1073	2144
Severe Vertebral Fracture			
A subject had a prevalent vertebral fracture if any vertebra from T4 to L4 had a grade of 3 at baseline			

based on an assessment of spinal radiographs using Genant Semiquantitative Scoring Method. Otherwise, a subject was considered absence of severe vertebral fracture at baseline.			
Units: Subjects			
Presence	1321	1369	2690
Absence	726	677	1403
Total Hip Bone Mineral Density (BMD) T-score			
BMD was measured using dual-energy x-ray absorptiometry (DXA). The T-score is a comparison of a person's bone density with that of a healthy 30-year-old of the same sex. Lower scores (more negative) mean lower bone density: A T-score of -2.5 or lower qualifies as osteoporosis and a T-score of -1.0 to -2.5 signifies osteopenia, meaning below-normal bone density without full osteoporosis.			
Units: Subjects			
≤ -2.5	1384	1356	2740
> -2.5	662	690	1352
Missing	1	0	1

## End points

### End points reporting groups

Reporting group title	Alendronate/Alendronate
Reporting group description: Participants received 70 mg alendronate once a week and placebo to romosozumab subcutaneously once a month for the first 12 months. After completion of the 12-month double-blind treatment period participants continued to receive 70 mg alendronate once a week until the end of the study.	
Reporting group title	Romosozumab/Alendronate
Reporting group description: Participants received 210 romosozumab mg subcutaneously once a month and placebo to alendronate orally once a week for the first 12 months. After completion of the 12-month double-blind treatment period participants received 70 mg alendronate once a week until the end of the study.	

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

End point title	Percentage of Participants with New Vertebral Fractures Through Month 24
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 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, greater than 40% reduction in anterior, middle, and/or posterior height.</li></ul> The analysis was conducted in randomized participants with a baseline and $\geq 1$ post-baseline evaluation of vertebral fracture at or before 24 months and includes participants who had vertebrae with missing Genant semiquantitative scores at baseline and whose first post-baseline spinal radiograph showed no fracture on the same vertebrae. Last observation carried forward imputation was used.	
End point type	Primary
End point timeframe: 24 months	

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1834	1825		
Units: percentage of participants				
number (not applicable)	8.0	4.1		

### Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659



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	0.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.36
upper limit	0.64
Variability estimate	Standard error of the mean
Dispersion value	0.15

Notes:

[1] - The primary endpoints were tested at the 5% level (2-sided), accounting for multiplicity using the Hochberg procedure. If the larger of the 2 P-values was significant at the 0.05 level (2-sided), the statistical testing continued to the secondary endpoint in the testing sequence.

[2] - Based on logistic regression model adjusted for age strata, baseline total hip BMD T-score and presence of severe vertebral fracture at baseline.

The standard error (SE) represents the standard error of log(odds ratio).

<b>Statistical analysis title</b>	Risk Ratio
Statistical analysis description:	
The risk ratio (ratio of proportions, Romosozumab over Alendronate) was based on the Mantel Haenszel method, adjusted for age strata (<75 vs. ≥75 years), the presence or absence of severe vertebral fracture at baseline, and baseline bone mineral density T score at the total hip (≤ -2.5, > -2.5). SE represents the standard error of log(risk ratio).	
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk ratio (RR)
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.66
Variability estimate	Standard error of the mean
Dispersion value	0.14

<b>Statistical analysis title</b>	Absolute Risk Reduction
Statistical analysis description:	
The absolute risk reduction (difference in proportions, alendronate – romosozumab) based on the Mantel-Haenszel method adjusted for age strata, baseline total hip BMD T-score (≤ -2.5, > -2.5), and presence of severe vertebral fracture at baseline.	
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority

Parameter estimate	Absolute risk reduction
Point estimate	4.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	0.78

### Primary: Percentage of Participants with a Clinical Fracture at the Primary Analysis

End point title	Percentage of Participants with a Clinical Fracture at the Primary Analysis
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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 analysis was conducted in all randomized participants. Missing values for clinical vertebral fractures were imputed using last observation carried forward.

End point type	Primary
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#### End point timeframe:

The primary analysis was performed when clinical fracture events had been confirmed in at least 330 patients and all participants had completed the month 24 visit. The median follow-up was 2.7 years (interquartile range, 2.2 to 3.3).

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	13.0	9.7		

### Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[3]</sup>
P-value	< 0.001 <sup>[4]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %

sides	2-sided
lower limit	0.61
upper limit	0.88
Variability estimate	Standard error of the mean
Dispersion value	0.09

Notes:

[3] - The primary endpoints were tested at the 5% level (2-sided), accounting for multiplicity using the Hochberg procedure. If the larger of the 2 P-values was significant at the 0.05 level (2-sided), the statistical testing continued to the secondary endpoint in the testing sequence.

[4] - Based on a Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.  
SE represents the standard error of log (hazard ratio).

## Secondary: Percentage of Participants with a Nonvertebral Fracture at the Primary Analysis

End point title	Percentage of Participants with a Nonvertebral Fracture at the Primary Analysis
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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 analysis was conducted in all randomized participants.

End point type	Secondary
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End point timeframe:

The primary analysis was performed when clinical fracture events had been confirmed in at least 330 patients and all participants had completed the month 24 visit. The median follow-up was 2.7 years (interquartile range, 2.2 to 3.3).

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	10.6	8.7		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[5]</sup>
P-value	= 0.04 <sup>[6]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.81
Confidence interval	
level	95 %

sides	2-sided
lower limit	0.66
upper limit	0.99
Variability estimate	Standard error of the mean
Dispersion value	0.1

Notes:

[5] - If the 2 primary endpoints and the specified BMD secondary endpoints were all significant, the nonvertebral fracture at the primary analysis was evaluated based on a 1-sided test (overall  $\alpha=0.025$ ) determined by the Lan-DeMets alpha spending function that approximates a Pocock boundary, 0.0233 (1-sided).

The adjusted 2-sided p-value is reported.

[6] - Based on a Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

## Secondary: Percentage of Participants with any Fracture at the Primary Analysis

End point title	Percentage of Participants with any Fracture at the Primary Analysis
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End point description:

All fractures include any osteoporotic nonvertebral fractures that are not associated with high trauma severity or pathologic fractures and new or worsening vertebral fractures regardless of trauma severity or pathologic fractures.

The analysis was conducted in all randomized participants.

End point type	Secondary
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End point timeframe:

The primary analysis was performed when clinical fracture events had been confirmed in at least 330 patients and all participants had completed the month 24 visit. The median follow-up was 2.7 years (interquartile range, 2.2 to 3.3).

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	19.1	13.0		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[7]</sup>
P-value	< 0.001 <sup>[8]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.56

upper limit	0.76
Variability estimate	Standard error of the mean
Dispersion value	0.08

Notes:

[7] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[8] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

## 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
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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.

The analysis was conducted in randomized participants with a baseline and  $\geq 1$  post-baseline evaluation of vertebral fracture at or before 24 months and includes participants who had vertebrae with missing Genant semiquantitative scores at baseline and whose first post-baseline spinal radiograph showed no fracture on the same vertebrae. Last observation carried forward imputation was used.

End point type	Secondary
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End point timeframe:

24 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1834	1825		
Units: percentage of participants				
number (not applicable)	9.2	4.8		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority <sup>[9]</sup>
P-value	< 0.001 <sup>[10]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	0.64
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:

[9] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[10] - Based on a logistic regression model adjusted for age strata, baseline total hip BMD T-score and presence of severe vertebral fracture at baseline; p-value based on score test.  
SE represents the standard error of log(odds ratio).

<b>Statistical analysis title</b>	Absolute Risk Reduction
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Statistical analysis description:

The absolute risk reduction (difference in proportions, Alendronate – Romosozumab) based on the Mantel-Haenszel method adjusted for age strata, baseline total hip BMD T-score ( $\leq -2.5$ ,  $> -2.5$ ), and presence of severe vertebral fracture at baseline.

Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Absolute Risk Reduction
Point estimate	4.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.8
upper limit	6.08
Variability estimate	Standard error of the mean
Dispersion value	0.84

<b>Statistical analysis title</b>	Risk Ratio
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Statistical analysis description:

The risk ratio (ratio of proportions, Romosozumab over Alendronate) was based on the Mantel Haenszel method, adjusted for age strata ( $<75$  vs.  $\geq 75$  years), the presence or absence of severe vertebral fracture at baseline, and baseline bone mineral density T score at the total hip ( $\leq -2.5$ ,  $> -2.5$ ).  
SE represents the standard error of log(risk ratio).

Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk ratio (RR)
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	0.66
Variability estimate	Standard error of the mean
Dispersion value	0.13

## Secondary: Percentage of Participants with a Major Nonvertebral Fracture at the Primary Analysis

End point title	Percentage of Participants with a Major Nonvertebral Fracture at the Primary Analysis
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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 analysis was conducted in all randomized participants.

End point type	Secondary
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End point timeframe:

The primary analysis was performed when clinical fracture events had been confirmed in at least 330 patients and all participants had completed the month 24 visit. The median follow-up was 2.7 years (interquartile range, 2.2 to 3.3).

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	9.6	7.1		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[11]</sup>
P-value	= 0.004 <sup>[12]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.9
Variability estimate	Standard error of the mean
Dispersion value	0.11

Notes:

[11] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[12] - Based on a Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

## Secondary: Percentage of Participants with a Hip Fracture at the Primary Analysis

End point title	Percentage of Participants with a Hip Fracture at the Primary Analysis
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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 analysis was conducted in all randomized participants.

End point type	Secondary
End point timeframe:	
The primary analysis was performed when clinical fracture events had been confirmed in at least 330 patients and all participants had completed the month 24 visit. The median follow-up was 2.7 years (interquartile range, 2.2 to 3.3).	

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	3.2	2.0		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[13]</sup>
P-value	= 0.015 <sup>[14]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	0.92
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:

[13] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[14] - Based on a Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

## 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 analysis was conducted in randomized participants with a baseline and  $\geq 1$  post-baseline evaluation of vertebral fracture at or before 24 months and includes participants who had vertebrae with missing Genant semiquantitative scores at baseline and whose first post-baseline spinal radiograph showed no fracture on the same vertebrae. Last observation carried forward imputation was used.



End point type	Secondary
End point timeframe:	
24 months	

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1834	1825		
Units: percentage of participants				
number (not applicable)	2.5	1.3		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority <sup>[15]</sup>
P-value	= 0.008 <sup>[16]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	0.85
Variability estimate	Standard error of the mean
Dispersion value	0.25

Notes:

[15] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[16] - Based on logistic regression model adjusted for age strata, baseline total hip BMD T-score and presence of severe vertebral fracture at baseline.

SE represents the standard error of log(odds ratio).

Statistical analysis title	Risk Ratio
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Statistical analysis description:

The risk ratio (ratio of proportions, Romosozumab over Alendronate) was based on the Mantel Haenszel method, adjusted for age strata (<75 vs. ≥75 years), the presence or absence of severe vertebral fracture at baseline, and baseline bone mineral density T score at the total hip ( $\leq -2.5$ ,  $> -2.5$ ).

SE represents the standard error of log(risk ratio).

Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk ratio (RR)

Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.32
upper limit	0.85
Variability estimate	Standard error of the mean
Dispersion value	0.25

<b>Statistical analysis title</b>	Absolute Risk Reduction
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Statistical analysis description:

The absolute risk reduction (difference in proportions, alendronate – romosozumab) based on the Mantel-Haenszel method adjusted for age strata, baseline total hip BMD T-score ( $\leq -2.5$ ,  $> -2.5$ ), and presence of severe vertebral fracture at baseline.

Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3659
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Absolute risk reduction
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	2.1
Variability estimate	Standard error of the mean
Dispersion value	0.45

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

End point title	Percentage of Participants with a Clinical Fracture Through Month 24
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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 analysis was conducted in all randomized participants. Missing values for clinical vertebral fractures were imputed using last observation carried forward.

End point type	Secondary
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End point timeframe:

24 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	9.6	7.1		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[17]</sup>
P-value	= 0.005 <sup>[18]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.91
Variability estimate	Standard error of the mean
Dispersion value	0.11

Notes:

[17] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[18] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.  
SE represents the standard error of log (hazard ratio).

## 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 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 analysis was conducted in all randomized participants.

End point type	Secondary
----------------	-----------

End point timeframe:

24 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	7.8	6.3		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[19]</sup>
P-value	= 0.074 <sup>[20]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	1.02
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[19] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[20] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.  
SE represents the standard error of log (hazard ratio).

## 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 analysis was conducted in all randomized participants.	
End point type	Secondary
End point timeframe:	
24 months	

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	2.1	1.5		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[21]</sup>
P-value	= 0.17 <sup>[22]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	1.15
Variability estimate	Standard error of the mean
Dispersion value	0.24

Notes:

[21] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[22] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.  
SE represents the standard error of log (hazard ratio).

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

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

A clinical vertebral fracture is a new or worsening vertebral fracture assessed at either a scheduled or unscheduled visit and associated with any signs and/or symptoms of back pain indicative of a fracture, regardless of trauma severity or whether it is pathologic.  
The analysis was conducted in all randomized participants. Last observation carried forward imputation was used.

End point type	Secondary
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End point timeframe:

24 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	2.1	0.9		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[23]</sup>
P-value	< 0.001 <sup>[24]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.24
upper limit	0.71
Variability estimate	Standard error of the mean
Dispersion value	0.28

Notes:

[23] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[24] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log(hazards ratio).

## 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 analysis was conducted in all randomized participants. Missing values for clinical vertebral fractures were imputed using last observation carried forward.

End point type	Secondary
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End point timeframe:

12 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	5.4	3.9		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[25]</sup>
P-value	= 0.027 <sup>[26]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	0.96
Variability estimate	Standard error of the mean
Dispersion value	0.15

Notes:

[25] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[26] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

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

End point title	Percentage of Participants with New Vertebral Fractures Through Month 12
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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 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, greater than 40% reduction in anterior, middle, and/or posterior height.

The analysis was conducted in randomized participants with a baseline and  $\geq 1$  post-baseline evaluation of vertebral fracture at or before 12 months and includes participants who had vertebrae with missing Genant semiquantitative scores at baseline and whose first post-baseline spinal radiograph showed no fracture on the same vertebrae. Last observation carried forward imputation was used.

End point type	Secondary
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End point timeframe:

12 months

<b>End point values</b>	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1703	1696		
Units: percentage of participants				
number (not applicable)	5.0	3.2		

## Statistical analyses

<b>Statistical analysis title</b>	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3399
Analysis specification	Pre-specified
Analysis type	superiority <sup>[27]</sup>
P-value	= 0.008 <sup>[28]</sup>
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.44
upper limit	0.89
Variability estimate	Standard error of the mean
Dispersion value	0.18

Notes:

[27] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[28] - Based on logistic regression model adjusted for age strata, baseline total hip BMD T-score and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (odds ratio).

<b>Statistical analysis title</b>	Risk Ratio
Statistical analysis description:	
The risk ratio (ratio of proportions, Romosozumab over Alendronate) was based on the Mantel Haenszel method, adjusted for age strata (<75 vs. ≥75 years), the presence or absence of severe vertebral fracture at baseline, and baseline bone mineral density T score at the total hip (≤ -2.5, > -2.5). SE represents the standard error of log (risk ratio).	
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3399
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Risk ratio (RR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46



upper limit	0.89
Variability estimate	Standard error of the mean
Dispersion value	0.17

<b>Statistical analysis title</b>	Absolute Risk Reduction
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Statistical analysis description:

The absolute risk reduction (difference in proportions, alendronate – romosozumab) based on the Mantel-Haenszel method adjusted for age strata, baseline total hip BMD T-score ( $\leq -2.5$ ,  $> -2.5$ ), and presence of severe vertebral fracture at baseline.

Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3399
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Absolute risk reduction
Point estimate	1.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	3.17
Variability estimate	Standard error of the mean
Dispersion value	0.68

## Secondary: Percentage of Participants with Any Fracture Through Month 12

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

All fractures include any osteoporotic nonvertebral fractures that are not associated with high trauma severity or pathologic fractures and new or worsening vertebral fractures regardless of trauma severity or pathologic fractures.

The analysis was conducted in all randomized participants.

End point type	Secondary
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End point timeframe:

12 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	9.2	6.5		

## Statistical analyses

<b>Statistical analysis title</b>	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[29]</sup>
P-value	= 0.002 <sup>[30]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.88
Variability estimate	Standard error of the mean
Dispersion value	0.11

Notes:

[29] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[30] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

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

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

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 analysis was conducted in all randomized participants.

End point type	Secondary
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End point timeframe:

12 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	4.6	3.4		

## Statistical analyses

<b>Statistical analysis title</b>	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate

Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[31]</sup>
P-value	= 0.057 <sup>[32]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.01
Variability estimate	Standard error of the mean
Dispersion value	0.16

Notes:

[31] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[32] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

## 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 analysis was conducted in all randomized participants.

End point type	Secondary
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End point timeframe:

12 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	1.1	0.7		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[33]</sup>
P-value	= 0.19 <sup>[34]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)

Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	1.26
Variability estimate	Standard error of the mean
Dispersion value	0.34

Notes:

[33] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[34] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

## 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
-----------------	--

End point description:

Major osteoporotic fractures included clinical vertebral fractures and fractures of the hip, forearm and humerus. Fractures associated with high trauma severity or pathologic fractures were excluded.

The analysis was conducted in all randomized participants.

End point type	Secondary
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End point timeframe:

12 months

End point values	Alendronate/Alendronate	Romsozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	4.2	3.0		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romsozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.053 <sup>[35]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52

upper limit	1.01
Variability estimate	Standard error of the mean
Dispersion value	0.17

Notes:

[35] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.

SE represents the standard error of log (hazard ratio).

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

End point title	Percentage of Participants with a Clinical Vertebral Fracture Through Month 12
-----------------	--

End point description:

A clinical vertebral fracture is a new or worsening vertebral fracture assessed at either a scheduled or unscheduled visit and associated with any signs and/or symptoms of back pain indicative of a fracture, regardless of trauma severity or whether it is pathologic.

The analysis was conducted in all randomized participants. Last observation carried forward imputation was used.

End point type	Secondary
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End point timeframe:

12 months

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2047	2046		
Units: percentage of participants				
number (not applicable)	0.9	0.5		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	4093
Analysis specification	Pre-specified
Analysis type	superiority <sup>[36]</sup>
P-value	= 0.14 <sup>[37]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	1.22
Variability estimate	Standard error of the mean
Dispersion value	0.39

Notes:

[36] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[37] - Based on Cox proportional hazards model adjusting for age strata, baseline total hip BMD T-score, and presence of severe vertebral fracture at baseline.  
SE represents the standard error of log (hazard ratio).

## 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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation during the open-label period at or before month 24; Missing values were imputed by carrying forward the last non-missing post-baseline value in the open-label treatment period prior to the missing value.

End point type	Secondary
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End point timeframe:

Baseline and month 24

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1577	1571		
Units: percent change				
least squares mean (standard error)	7.2 ( $\pm$ 0.2)	15.3 ( $\pm$ 0.2)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3148
Analysis specification	Pre-specified
Analysis type	superiority <sup>[38]</sup>
P-value	< 0.001 <sup>[39]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.58
upper limit	8.57
Variability estimate	Standard error of the mean
Dispersion value	0.3

Notes:

[38] - If the differences in both primary end points were significant with the use of the Hochberg procedure, a fixed-sequence testing procedure was used for bone mineral density and the key secondary end point of nonvertebral fracture to adjust for multiple comparisons and to maintain an overall significance level of 0.05.

[39] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type interaction.

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

End point title	Percent Change from Baseline in Bone Mineral Density of the Total Hip 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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation during the open-label period at or before month 24; Missing values were imputed by carrying forward the last non-missing post-baseline value in the open-label treatment period prior to the missing value.

End point type	Secondary
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End point timeframe:

Baseline and month 24

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1627	1622		
Units: percent change				
least squares mean (standard error)	3.5 ( $\pm$ 0.1)	7.2 ( $\pm$ 0.1)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3249
Analysis specification	Pre-specified
Analysis type	superiority <sup>[40]</sup>
P-value	< 0.001 <sup>[41]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.42
upper limit	4.1
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:

[40] - If the differences in both primary end points were significant with the use of the Hochberg procedure, a fixed-sequence testing procedure was used for bone mineral density and the key secondary end point of nonvertebral fracture to adjust for multiple comparisons and to maintain an overall significance level of 0.05.

[41] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type interaction.

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

End point title	Percent Change from Baseline in Bone Mineral Density of the Femoral Neck 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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation during the open-label period at or before month 24; Missing values were imputed by carrying forward the last non-missing post-baseline value in the open-label treatment period prior to the missing value.

End point type	Secondary
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End point timeframe:

Baseline and month 24

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1627	1622		
Units: percent change				
least squares mean (standard error)	2.3 ( $\pm$ 0.2)	6.0 ( $\pm$ 0.2)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3249
Analysis specification	Pre-specified
Analysis type	superiority <sup>[42]</sup>
P-value	< 0.001 <sup>[43]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.4
upper limit	4.14
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:

[42] - If the differences in both primary end points were significant with the use of the Hochberg procedure, a fixed-sequence testing procedure was used for bone mineral density and the key secondary end point of nonvertebral fracture to adjust for multiple comparisons and to maintain an overall significance level of 0.05.



[43] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type interaction.

## 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
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 analysis was conducted in all randomized participants with a baseline and $\geq 1$ post-baseline evaluation at or before month 12; Last observation carried forward imputation was used.	
End point type	Secondary
End point timeframe:	
Baseline and month 12	

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1718	1722		
Units: percent change				
least squares mean (standard error)	5.0 ( $\pm$ 0.1)	13.7 ( $\pm$ 0.2)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3440
Analysis specification	Pre-specified
Analysis type	superiority <sup>[44]</sup>
P-value	< 0.001 <sup>[45]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.31
upper limit	9.09
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:

[44] - If the differences in both primary end points were significant with the use of the Hochberg procedure, a fixed-sequence testing procedure was used for bone mineral density and the key secondary end point of nonvertebral fracture to adjust for multiple comparisons and to maintain an overall significance level of 0.05.

[45] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type

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

End point title	Percent Change from Baseline in Bone Mineral Density of the Total Hip 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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation at or before month 12; Last observation carried forward imputation was used.

End point type	Secondary
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End point timeframe:

Baseline and month 12

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1781	1781		
Units: percent change				
least squares mean (standard error)	2.8 ( $\pm$ 0.1)	6.2 ( $\pm$ 0.1)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3562
Analysis specification	Pre-specified
Analysis type	superiority <sup>[46]</sup>
P-value	< 0.001 <sup>[47]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.03
upper limit	3.6
Variability estimate	Standard error of the mean
Dispersion value	0.1

Notes:

[46] - If the differences in both primary end points were significant with the use of the Hochberg procedure, a fixed-sequence testing procedure was used for bone mineral density and the key secondary end point of nonvertebral fracture to adjust for multiple comparisons and to maintain an overall significance level of 0.05.

[47] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type

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

End point title	Percent Change from Baseline in Bone Mineral Density of the Femoral Neck 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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation at or before month 12; Last observation carried forward imputation was used.

End point type	Secondary
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End point timeframe:

Baseline and month 12

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1781	1781		
Units: percent change				
least squares mean (standard error)	1.7 ( $\pm$ 0.1)	4.9 ( $\pm$ 0.1)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3562
Analysis specification	Pre-specified
Analysis type	superiority <sup>[48]</sup>
P-value	< 0.001 <sup>[49]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.9
upper limit	3.54
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:

[48] - If the differences in both primary end points were significant with the use of the Hochberg procedure, a fixed-sequence testing procedure was used for bone mineral density and the key secondary end point of nonvertebral fracture to adjust for multiple comparisons and to maintain an overall significance level of 0.05.

[49] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type

## Secondary: Percent Change from Baseline in Bone Mineral Density at the Lumbar Spine at Month 36

End point title	Percent Change from Baseline in Bone Mineral Density at the Lumbar Spine at Month 36
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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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation during the open-label period at or before month 36; Missing values were imputed by carrying forward the last non-missing post-baseline value in the open-label treatment period prior to the missing value.

End point type	Secondary
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End point timeframe:

Baseline and month 36

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1597	1593		
Units: percent change				
least squares mean (standard error)	7.8 ( $\pm$ 0.2)	15.2 ( $\pm$ 0.2)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3190
Analysis specification	Pre-specified
Analysis type	superiority <sup>[50]</sup>
P-value	< 0.001 <sup>[51]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.84
upper limit	7.89
Variability estimate	Standard error of the mean
Dispersion value	0.3

Notes:

[50] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[51] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type

## Secondary: Percent Change from Baseline in Bone Mineral Density of the Total Hip at Month 36

End point title	Percent Change from Baseline in Bone Mineral Density of the Total Hip at Month 36
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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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation during the open-label period at or before month 36; Missing values were imputed by carrying forward the last non-missing post-baseline value in the open-label treatment period prior to the missing value.

End point type	Secondary
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End point timeframe:

Baseline and month 36

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1653	1653		
Units: percent change				
least squares mean (standard error)	3.5 ( $\pm$ 0.1)	7.2 ( $\pm$ 0.1)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3306
Analysis specification	Pre-specified
Analysis type	superiority <sup>[52]</sup>
P-value	< 0.001 <sup>[53]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.29
upper limit	4.02
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:

[52] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[53] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type

## Secondary: Percent Change from Baseline in Bone Mineral Density of the Femoral Neck at Month 36

End point title	Percent Change from Baseline in Bone Mineral Density of the Femoral Neck at Month 36
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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 analysis was conducted in all randomized participants with a baseline and  $\geq 1$  post-baseline evaluation during the open-label period at or before month 36; Missing values were imputed by carrying forward the last non-missing post-baseline value in the open-label treatment period prior to the missing value.

End point type	Secondary
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End point timeframe:

Baseline and month 36

End point values	Alendronate/Alendronate	Romosozumab/Alendronate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1653	1653		
Units: percent change				
least squares mean (standard error)	2.4 ( $\pm$ 0.2)	6.0 ( $\pm$ 0.2)		

## Statistical analyses

Statistical analysis title	Primary Analysis
Comparison groups	Alendronate/Alendronate v Romosozumab/Alendronate
Number of subjects included in analysis	3306
Analysis specification	Pre-specified
Analysis type	superiority <sup>[54]</sup>
P-value	< 0.001 <sup>[55]</sup>
Method	ANCOVA
Parameter estimate	LS Mean Difference
Point estimate	3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.18
upper limit	3.97
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:

[54] - This endpoint was not included in the sequential testing procedure and was analyzed without multiplicity adjustment at a significance level of 0.05 (two-sided).

[55] - Based on ANCOVA model adjusting for treatment, age strata, presence of severe vertebral fracture at baseline, baseline BMD value, machine type, and baseline BMD value-by-machine type



## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

The 12-month double-blind treatment phase and overall study period which includes AEs up to the end of study for subjects who received an open-label dose and up to 12 months for subjects who did not; overall median duration of follow-up was 36 months.

Adverse event reporting additional description:

The safety analysis set included all randomized subjects who received  $\geq 1$  active dose of investigational product in the 12-month double-blind alendronate-controlled study period. Two participants randomized to alendronate received romosozumab in error and are counted in the romosozumab group for safety.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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### Reporting groups

Reporting group title	12-Month Double-blind Period: Alendronate 70 mg QW
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Reporting group description:

Participants received 70 mg alendronate once a week (QW) and placebo to romosozumab subcutaneously once a month for 12 months during the double-blind treatment period.

Reporting group title	Overall Study: Alendronate / Alendronate
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Reporting group description:

Participants received 70 mg alendronate once a week and placebo to romosozumab subcutaneously once a month for the first 12 months. After completion of the 12-month double-blind treatment period participants continued to receive 70 mg alendronate once a week until the end of the study.

Reporting group title	Overall Study: Romosozumab / Alendronate
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Reporting group description:

Participants received 210 romosozumab mg subcutaneously once a month and placebo to alendronate orally once a week for the first 12 months. After completion of the 12-month double-blind treatment period participants received 70 mg alendronate once a week until the end of the study.

Reporting group title	12-Month Double-blind Period: Romosozumab 210 mg QM
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Reporting group description:

Participants received 210 mg romosozumab subcutaneously once a month (QM) and placebo to alendronate orally once a week for the first 12 months during the double-blind treatment period.

Serious adverse events	12-Month Double-blind Period: Alendronate 70 mg QW	Overall Study: Alendronate / Alendronate	Overall Study: Romosozumab / Alendronate
Total subjects affected by serious adverse events			
subjects affected / exposed	278 / 2014 (13.80%)	638 / 2014 (31.68%)	611 / 2040 (29.95%)
number of deaths (all causes)	22	103	101
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Burns third degree			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Carbon monoxide poisoning			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Clavicle fracture			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 2014 (0.05%)	7 / 2014 (0.35%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 bones fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	4 / 2014 (0.20%)	11 / 2014 (0.55%)	13 / 2040 (0.64%)
occurrences causally related to treatment / all	0 / 5	0 / 13	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Femoral neck fracture			
subjects affected / exposed	12 / 2014 (0.60%)	31 / 2014 (1.54%)	15 / 2040 (0.74%)
occurrences causally related to treatment / all	0 / 12	1 / 31	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Femur fracture			
subjects affected / exposed	12 / 2014 (0.60%)	51 / 2014 (2.53%)	42 / 2040 (2.06%)
occurrences causally related to treatment / all	0 / 12	2 / 51	3 / 45
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fibula fracture			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 4	0 / 9	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	3 / 2014 (0.15%)	5 / 2014 (0.25%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured ischium			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Fractured sacrum			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 anastomotic leak			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft complication			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	7 / 2014 (0.35%)	16 / 2014 (0.79%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 7	0 / 16	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ilium fracture			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 injury			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Laceration			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 2014 (0.05%)	8 / 2014 (0.40%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Patella fracture			
subjects affected / exposed	0 / 2014 (0.00%)	5 / 2014 (0.25%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post laminectomy syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis fracture			
subjects affected / exposed	4 / 2014 (0.20%)	7 / 2014 (0.35%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 4	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	12 / 2014 (0.60%)	20 / 2014 (0.99%)	14 / 2040 (0.69%)
occurrences causally related to treatment / all	0 / 12	0 / 20	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Scapula fracture			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 2014 (0.00%)	5 / 2014 (0.25%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	5 / 2014 (0.25%)	8 / 2014 (0.40%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 5	0 / 8	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	6 / 2014 (0.30%)	11 / 2014 (0.55%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 6	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 evisceration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoembryonic antigen increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulation time prolonged			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Heart rate decreased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical observation normal			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 function test abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Weight decreased subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction subjects affected / exposed	2 / 2014 (0.10%)	15 / 2014 (0.74%)	16 / 2040 (0.78%)
occurrences causally related to treatment / all	0 / 2	0 / 19	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 5	0 / 5
Angina pectoris subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	7 / 2040 (0.34%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Angina unstable subjects affected / exposed	2 / 2014 (0.10%)	7 / 2014 (0.35%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	1 / 2	1 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia supraventricular			

subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Arteriospasm coronary			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.20%)	17 / 2014 (0.84%)	12 / 2040 (0.59%)
occurrences causally related to treatment / all	0 / 5	2 / 19	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	1 / 3	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bradycardia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Cardiac disorder			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure			
subjects affected / exposed	5 / 2014 (0.25%)	25 / 2014 (1.24%)	18 / 2040 (0.88%)
occurrences causally related to treatment / all	0 / 6	0 / 31	0 / 22
deaths causally related to treatment / all	0 / 1	0 / 5	0 / 3
Cardiac failure acute			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure chronic			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	2 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	5 / 2014 (0.25%)	12 / 2014 (0.60%)	9 / 2040 (0.44%)
occurrences causally related to treatment / all	0 / 7	0 / 15	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 4	0 / 2
Cardiac tamponade			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac valve disease			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiogenic shock			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4

deaths causally related to treatment / all	0 / 0	0 / 1	0 / 3
Cardiomyopathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Cardiopulmonary failure			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 1
Coronary artery disease			
subjects affected / exposed	0 / 2014 (0.00%)	5 / 2014 (0.25%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mitral valve incompetence			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial fibrosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myocardial infarction			
subjects affected / exposed	3 / 2014 (0.15%)	8 / 2014 (0.40%)	8 / 2040 (0.39%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Myocardial ischaemia			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Palpitations			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood and lymphatic system disorders			
Anaemia of chronic disease			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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	3 / 2014 (0.15%)	9 / 2014 (0.45%)	7 / 2040 (0.34%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic anaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to	0 / 0	0 / 1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic anaemia			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amnesia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic lateral sclerosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid aneurysm rupture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid arteriosclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	7 / 2014 (0.35%)	15 / 2014 (0.74%)	19 / 2040 (0.93%)
occurrences causally related to treatment / all	1 / 8	1 / 17	0 / 21
deaths causally related to treatment / all	1 / 2	1 / 3	0 / 4
Cerebrovascular disorder			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dementia Alzheimer's type			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	3 / 2014 (0.15%)	7 / 2014 (0.35%)	9 / 2040 (0.44%)
occurrences causally related to treatment / all	0 / 3	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Essential tremor			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Extrapyramidal disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 paralysis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

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	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemorrhagic stroke			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Hemiparesis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypokinesia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ischaemic neuropathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	3 / 2014 (0.15%)	10 / 2014 (0.50%)	10 / 2040 (0.49%)
occurrences causally related to treatment / all	0 / 4	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Loss of consciousness			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbosacral radiculopathy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Memory impairment			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mixed dementia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoparesis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Multiple sclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis relapse			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve root compression			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paresis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

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 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic epilepsy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stroke in evolution			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	4 / 2014 (0.20%)	10 / 2014 (0.50%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 4	0 / 11	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Toxic encephalopathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	2 / 2014 (0.10%)	5 / 2014 (0.25%)	11 / 2040 (0.54%)
occurrences causally related to treatment / all	0 / 2	0 / 5	1 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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	4 / 2014 (0.20%)	9 / 2014 (0.45%)	11 / 2040 (0.54%)
occurrences causally related to treatment / all	0 / 4	0 / 10	2 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine ophthalmopathy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Entropion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neovascular age-related macular degeneration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 artery thrombosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Strabismus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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			
Vertigo			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal incontinence			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal polyp			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive oesophagitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral hernia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral hernia incarcerated			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.05%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 1	1 / 3	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 2014 (0.05%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	1 / 1	2 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal haemorrhage subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal inflammation subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Inguinal hernia subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal ulcer			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal ulcer			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric arterial occlusion subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Nausea subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal ulcer subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis acute			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer perforation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Peritoneal adhesions			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland calculus			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	5 / 2040 (0.25%)



occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	1 / 1	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	9 / 2040 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	3 / 2014 (0.15%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haematuria			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nephritis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to	0 / 0	0 / 0	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 failure			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Stress urinary incontinence			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 bladder haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral polyp			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 breakage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device failure			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 contact			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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 ulcer			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	9 / 2014 (0.45%)	17 / 2014 (0.84%)	11 / 2040 (0.54%)
occurrences causally related to treatment / all	0 / 9	0 / 18	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extraskeletal ossification			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Foot deformity			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture pain			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc displacement			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Muscular weakness			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	5 / 2014 (0.25%)	11 / 2014 (0.55%)	19 / 2040 (0.93%)
occurrences causally related to treatment / all	0 / 5	0 / 11	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis of jaw			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)

occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in jaw			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to	0 / 1	0 / 1	0 / 1

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercorticism			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic goitre			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Electrolyte imbalance			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 / 2014 (0.10%)	5 / 2014 (0.25%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyponatraemia			
subjects affected / exposed	2 / 2014 (0.10%)	7 / 2014 (0.35%)	7 / 2040 (0.34%)
occurrences causally related to treatment / all	0 / 2	0 / 8	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			

subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	0 / 2040 (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
Appendicitis perforated			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	3 / 2014 (0.15%)	8 / 2014 (0.40%)	11 / 2040 (0.54%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchitis bacterial			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis infected			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Diverticulitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis bacterial			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Erysipelas			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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	2 / 2014 (0.10%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 6	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 C			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Herpes zoster			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected fistula			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Kidney infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Lung infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nosocomial infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Osteomyelitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreas infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal abscess			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	17 / 2014 (0.84%)	46 / 2014 (2.28%)	54 / 2040 (2.65%)
occurrences causally related to treatment / all	1 / 18	1 / 50	0 / 59
deaths causally related to treatment / all	1 / 4	1 / 9	0 / 8
Pneumonia bacterial			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural sepsis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 abscess			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0

Septic shock			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Sialoadenitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	8 / 2014 (0.40%)	21 / 2014 (1.04%)	21 / 2040 (1.03%)
occurrences causally related to treatment / all	0 / 8	0 / 26	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Viral diarrhoea			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic aneurysm rupture			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Aortic arteriosclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to	0 / 0	0 / 0	0 / 2

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure inadequately controlled			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Deep vein thrombosis			
subjects affected / exposed	5 / 2014 (0.25%)	9 / 2014 (0.45%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 5	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism arterial			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	4 / 2014 (0.20%)	8 / 2014 (0.40%)	8 / 2040 (0.39%)
occurrences causally related to treatment / all	0 / 4	0 / 10	0 / 8

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Hypovolaemic shock			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labile hypertension			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peripheral artery aneurysm			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 occlusion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 thrombosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 embolism			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phlebitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery occlusion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)

occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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			
Hip arthroplasty			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Umbilical hernia repair			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma gastric			

subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Anal cancer			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 cell carcinoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign breast neoplasm			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lung neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 renal neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)



occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Bladder squamous cell carcinoma stage unspecified			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer female			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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			
subjects affected / exposed	0 / 2014 (0.00%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cervix carcinoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0

deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Central nervous system neoplasm subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma stage IV subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	1 / 1	0 / 0
Cholangiocarcinoma subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 lymphocytic leukaemia subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choroid melanoma subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Colorectal carcinoma stage 0 subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial cancer subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epithelioid mesothelioma subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular thyroid cancer subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 carcinoma subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 stromal tumour subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal tract adenoma subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary cancer			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypopharyngeal cancer			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemangioma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular melanoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive breast carcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung adenocarcinoma stage 0			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lymphoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of renal pelvis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinum neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Meningioma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to adrenals			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

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 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 pancreas			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
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 peritoneum			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 bronchial carcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myeloproliferative neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 1
Neuroendocrine tumour			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma unspecified histology indolent stage I			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal adenocarcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ovarian adenoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cancer metastatic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 carcinoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Pancreatic neoplasm				
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Papillary cystadenoma lymphomatosum				
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Parathyroid tumour benign				
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Plasma cell myeloma				
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Rectal adenocarcinoma				
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Rectal cancer				
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)	
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 cancer				
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Renal neoplasm				
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0	
Retroperitoneal neoplasm				

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seborrhoeic keratosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
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 intestine carcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Squamous cell carcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of pharynx			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

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 the cervix			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the vulva			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine cancer			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Uterine leiomyoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Amyloidosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Limb prosthesis user			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of personal independence in daily activities			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Adverse event			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Asthenia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	2 / 2014 (0.10%)	21 / 2014 (1.04%)	14 / 2040 (0.69%)
occurrences causally related to treatment / all	0 / 2	1 / 21	0 / 14
deaths causally related to treatment / all	0 / 2	1 / 21	0 / 14

Feeling abnormal			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Impaired healing			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (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
Malaise			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strangulated hernia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	6 / 2040 (0.29%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 6
Ulcer haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to	0 / 0	0 / 1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Confusional state			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomania			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colpocele			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0



deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterovaginal prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute respiratory failure			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Asthma			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	10 / 2014 (0.50%)	29 / 2014 (1.44%)	24 / 2040 (1.18%)
occurrences causally related to treatment / all	0 / 12	0 / 44	0 / 33
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Bronchitis chronic			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic respiratory failure			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 2014 (0.00%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Emphysema			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranasal cyst			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 aspiration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumothorax			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 congestion			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 2	0 / 4	1 / 3

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sarcoidosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory acidosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (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
Respiratory distress			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory failure			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Sleep apnoea syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord cyst			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Ampulla of Vater stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary cirrhosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Biliary colic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary fibrosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cholecystitis chronic			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cholelithiasis			
subjects affected / exposed	6 / 2014 (0.30%)	9 / 2014 (0.45%)	7 / 2040 (0.34%)
occurrences causally related to treatment / all	0 / 6	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
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 cholestatic			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	12-Month Double-blind Period: Romosozumab 210 mg QM		
Total subjects affected by serious adverse events			
subjects affected / exposed	262 / 2040 (12.84%)		
number of deaths (all causes)	30		

number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Burns third degree			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Carbon monoxide poisoning			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Craniocerebral injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extradural haematoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		



deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				
subjects affected / exposed	5 / 2040 (0.25%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 1			
Femur fracture				
subjects affected / exposed	11 / 2040 (0.54%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
subjects affected / exposed	3 / 2040 (0.15%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foreign body				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured ischium				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Fractured sacrum				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal anastomotic leak				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Graft complication				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hand fracture				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	3 / 2040 (0.15%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Ilium fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incisional hernia				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint injury				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laceration				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament sprain				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb injury				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lip injury				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar vertebral fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meniscus injury				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle rupture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Patella fracture				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Post laminectomy syndrome				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural bile leak				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pubis fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	8 / 2040 (0.39%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Road traffic accident				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scapula fracture				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue injury				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stoma site haemorrhage				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haematoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ulna fracture			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound evisceration			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0		
Wrist fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carcinoembryonic antigen increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coagulation time prolonged			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart rate decreased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Medical observation normal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0		
Liver function test abnormal subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight decreased subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute left ventricular failure subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myocardial infarction subjects affected / exposed	8 / 2040 (0.39%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 3		
Angina pectoris subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Angina unstable subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Aortic valve stenosis subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		



deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia supraventricular				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arteriospasm coronary				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	3 / 2040 (0.15%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradyarrhythmia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cardiac arrest				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorder				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	5 / 2040 (0.25%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 2			
Cardiac failure acute				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure chronic				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cardiac tamponade				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac valve disease				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiogenic shock			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiopulmonary failure			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Coronary artery disease			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery occlusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Myocardial fibrosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	5 / 2040 (0.25%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	3 / 2040 (0.15%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Palpitations				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus bradycardia				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress cardiomyopathy				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Supraventricular extrasystoles subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Blood and lymphatic system disorders			
Anaemia of chronic disease subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaemia subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaemia vitamin B12 deficiency			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic anaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypochromic anaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leukopenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Microcytic anaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenomegaly			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amnesia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid aneurysm rupture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid arteriosclerosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid artery stenosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to	0 / 1		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Carpal tunnel syndrome				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral arteriosclerosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haematoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral ischaemia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	6 / 2040 (0.29%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 1			
Cerebrovascular disorder				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			



deaths causally related to treatment / all	0 / 0			
Dementia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dementia Alzheimer's type				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Embolic stroke				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	3 / 2040 (0.15%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Essential tremor				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extrapyramidal disorder				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Facial paralysis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised tonic-clonic seizure				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic stroke				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Hemiparesis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocephalus				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokinesia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotonia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intracranial aneurysm				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic cerebral infarction			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Ischaemic neuropathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Memory impairment			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mixed dementia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Monoparesis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple sclerosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple sclerosis relapse				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nerve root compression				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorder				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuralgia				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Optic neuritis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Paraparesis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paresis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parkinson's disease				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post-traumatic epilepsy				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Somnolence				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Speech disorder				
subjects affected / exposed	1 / 2040 (0.05%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stroke in evolution			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Toxic encephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences causally related to treatment / all	1 / 6		
deaths causally related to treatment / all	0 / 0		
Vascular encephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Amaurosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences causally related to	2 / 4		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Diplopia				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Endocrine ophthalmopathy				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Entropion				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glaucoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Macular fibrosis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neovascular age-related macular degeneration				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal artery thrombosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal detachment				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0		
Retinal haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Strabismus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Visual impairment			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitreous prolapse			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vertigo positional			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular ataxia			
subjects affected / exposed	0 / 2040 (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 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		



deaths causally related to treatment / all	0 / 0			
Abdominal hernia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	2 / 4			
deaths causally related to treatment / all	0 / 0			
Anal incontinence				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic gastritis				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Crohn's disease				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Diarrhoea				
subjects affected / exposed	4 / 2040 (0.20%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal haemorrhagic				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal polyp				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer perforation				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspepsia				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erosive oesophagitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femoral hernia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral hernia incarcerated			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food poisoning			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal inflammation				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			

Inguinal hernia strangulated subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal haemorrhage subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intestinal ulcer subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intra-abdominal haemorrhage subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intussusception subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Irritable bowel syndrome subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal stenosis subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal ulcer subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine polyp				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mechanical ileus				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesenteric arterial occlusion				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstruction gastric				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal ulcer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer perforation				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritoneal adhesions				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Peritoneal haemorrhage				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal prolapse				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Salivary gland calculus			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Volvulus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Bladder prolapse			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus bladder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			



subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nephritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 2040 (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 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral polyp			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device breakage			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device dislocation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device failure			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device malfunction			
subjects affected / exposed	0 / 2040 (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	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Decubitus ulcer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermatitis			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Dermatitis contact</b>			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Eczema</b>			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Skin ulcer</b>			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthralgia</b>			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
<b>Arthritis</b>			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Arthropathy</b>			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
<b>Back pain</b>			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
<b>Cervical spinal stenosis</b>			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extraskkeletal ossification				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot deformity				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fracture pain				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin pain				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc displacement				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mobility decreased				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	6 / 2040 (0.29%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Osteochondrosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis of jaw				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pain in extremity				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rheumatoid arthritis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in jaw				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal column stenosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Spinal pain				
subjects affected / exposed	3 / 2040 (0.15%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Spondylolisthesis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendonitis				
subjects affected / exposed	1 / 2040 (0.05%)			

occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercorticism			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperparathyroidism			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthyroidism			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Toxic goitre			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fluid overload			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		



deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Iron deficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Abdominal sepsis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal wall abscess				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis perforated				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis bacterial				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Campylobacter gastroenteritis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Cholecystitis infective				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dermatitis infected				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Empyema				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis bacterial				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis viral				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematoma infection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Hepatitis C				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected bite				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected fistula				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 2040 (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	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Kidney infection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Nosocomial infection				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media chronic				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreas infection				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pharyngeal abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	16 / 2040 (0.78%)		
occurrences causally related to treatment / all	0 / 17		
deaths causally related to treatment / all	0 / 1		
Pneumonia bacterial			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural sepsis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		

deaths causally related to treatment / all	0 / 0			
Pseudomembranous colitis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pseudomonal sepsis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyoderma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rhinitis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			



Sepsis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Sialoadenitis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subcutaneous abscess				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tracheobronchitis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	8 / 2040 (0.39%)			

occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Viral diarrhoea subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic aneurysm subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Aortic aneurysm rupture subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic arteriosclerosis subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to	0 / 1		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Aortic dissection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic stenosis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood pressure inadequately controlled				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Circulatory collapse				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Deep vein thrombosis				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Embolism arterial				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extremity necrosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive emergency				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Hypovolaemic shock				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intermittent claudication				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Labile hypertension				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orthostatic hypotension				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Peripheral arterial occlusive disease subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Peripheral artery aneurysm subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery occlusion subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery thrombosis subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral embolism subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Phlebitis subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Shock haemorrhagic subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subclavian artery occlusion subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombophlebitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Hip arthroplasty			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hospitalisation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgery			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia repair			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma gastric			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal cancer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
B-cell lymphoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	0 / 2040 (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 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign lung neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign renal neoplasm				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder cancer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder squamous cell carcinoma stage unspecified				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Breast cancer female				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Breast cancer metastatic				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			



deaths causally related to treatment / all	0 / 0			
Cervix carcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Central nervous system neoplasm				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervix carcinoma stage IV				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangiocarcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic lymphocytic leukaemia				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Choroid melanoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon adenoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colorectal adenocarcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Colon cancer				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Colorectal carcinoma stage 0				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial adenocarcinoma				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diffuse large B-cell lymphoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial cancer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epithelioid mesothelioma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Follicular thyroid cancer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal carcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal stromal tumour				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal tract adenoma				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic cancer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary cancer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hodgkin's disease				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypopharyngeal cancer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal adenocarcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intra-abdominal haemangioma				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intraductal papillary mucinous neoplasm				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			

deaths causally related to treatment / all	0 / 0			
Intraductal proliferative breast lesion				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intraocular melanoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive breast carcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipoma				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lung adenocarcinoma stage 0				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Lung neoplasm malignant subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphoma subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma in situ subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant neoplasm of renal pelvis subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mediastinum neoplasm subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningioma subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningioma benign subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to adrenals subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to bone			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to liver			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Metastases to lung			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to pancreas			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to peritoneum			
subjects affected / exposed	0 / 2040 (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 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastatic neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Myeloproliferative neoplasm subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neoplasm malignant subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine tumour subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's lymphoma subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's lymphoma unspecified histology indolent stage I subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal adenocarcinoma subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian adenoma subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cancer metastatic subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Pancreatic carcinoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic neoplasm				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papillary cystadenoma lymphomatosum				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parathyroid tumour benign				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Plasma cell myeloma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal adenocarcinoma				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal cancer				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cancer				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal neoplasm				



subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retroperitoneal neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seborrhoeic keratosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin cancer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small cell lung cancer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestine carcinoma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Squamous cell carcinoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of pharynx			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the cervix				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the oral cavity				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of the vulva				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureteric cancer				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine cancer				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Uterine leiomyoma				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Amyloidosis				

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug hypersensitivity			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Limb prosthesis user			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Loss of personal independence in daily activities			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse event			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Death				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Feeling abnormal				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypothermia				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired healing				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral swelling			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Strangulated hernia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ulcer haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vessel puncture site haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to	0 / 1		

treatment / all				
deaths causally related to treatment / all	0 / 0			
Alcohol withdrawal syndrome				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Completed suicide				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Confusional state				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Disorientation				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			

deaths causally related to treatment / all	0 / 0		
Hypomania			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mental disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schizophrenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colpocoele			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cystocoele			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Dysfunctional uterine bleeding subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pelvic haematoma subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postmenopausal haemorrhage subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pelvic prolapse subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine polyp subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine prolapse subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Uterovaginal prolapse subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			



Vaginal prolapse				
subjects affected / exposed	0 / 2040 (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	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Asthmatic crisis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	5 / 2040 (0.25%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Bronchitis chronic				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic respiratory failure				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Dyspnoea				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Emphysema				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Idiopathic pulmonary fibrosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Interstitial lung disease				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Obstructive airways disorder				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paranasal cyst				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleurisy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary congestion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary fibrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary mass			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Pulmonary sarcoidosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory acidosis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory arrest				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Respiratory failure				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sleep apnoea syndrome				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vocal cord cyst				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Hepatobiliary disorders			
Ampulla of Vater stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bile duct stone			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary cirrhosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary colic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary fibrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis acute			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis chronic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cirrhosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaundice cholestatic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

<b>Non-serious adverse events</b>	12-Month Double-blind Period: Alendronate 70 mg QW	Overall Study: Alendronate / Alendronate	Overall Study: Romosozumab / Alendronate
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1545 / 2014 (76.71%)	1739 / 2014 (86.35%)	1714 / 2040 (84.02%)
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Abdominal wound dehiscence			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Accident			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Accident at home			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Accidental exposure to product			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Accidental overdose			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Acetabulum fracture			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Anaemia postoperative			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	2	3	6
Animal bite			
subjects affected / exposed	5 / 2014 (0.25%)	14 / 2014 (0.70%)	11 / 2040 (0.54%)
occurrences (all)	5	14	11
Arterial injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Arthropod bite			
subjects affected / exposed	3 / 2014 (0.15%)	8 / 2014 (0.40%)	10 / 2040 (0.49%)
occurrences (all)	3	9	11
Arthropod sting			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	0	3	0
Back injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	0	1	4
Bladder injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Bone contusion			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	1 / 2040 (0.05%)
occurrences (all)	3	6	1
Brain contusion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Burns first degree			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Burns second degree			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	1	2	3
Chemical burn of skin			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Chemical cystitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Chemical poisoning			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Chest injury			
subjects affected / exposed	8 / 2014 (0.40%)	33 / 2014 (1.64%)	6 / 2040 (0.29%)
occurrences (all)	8	34	6



Chillblains			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Clavicle fracture			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Commotio retinae			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	1	5	2
Confusion postoperative			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	71 / 2014 (3.53%)	161 / 2014 (7.99%)	115 / 2040 (5.64%)
occurrences (all)	84	242	154
Corneal abrasion			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	6
Craniocerebral injury			
subjects affected / exposed	0 / 2014 (0.00%)	5 / 2014 (0.25%)	10 / 2040 (0.49%)
occurrences (all)	0	5	10
Deep vein thrombosis postoperative			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Dislocation of vertebra			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ear canal injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ear canal abrasion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0

Ear injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Epicondylitis			
subjects affected / exposed	8 / 2014 (0.40%)	13 / 2014 (0.65%)	3 / 2040 (0.15%)
occurrences (all)	9	14	4
Epidural haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Excoriation			
subjects affected / exposed	3 / 2014 (0.15%)	9 / 2014 (0.45%)	4 / 2040 (0.20%)
occurrences (all)	6	13	4
Eye contusion			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Eye injury			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Eyelid contusion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Face injury			
subjects affected / exposed	8 / 2014 (0.40%)	13 / 2014 (0.65%)	10 / 2040 (0.49%)
occurrences (all)	8	13	12
Facial bones fracture			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	2	3	2
Fall			
subjects affected / exposed	151 / 2014 (7.50%)	342 / 2014 (16.98%)	287 / 2040 (14.07%)
occurrences (all)	192	587	479
Fat overload syndrome			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Femoral neck fracture			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)

occurrences (all)	1	2	0
Femur fracture			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	1	3	1
Fibula fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	7 / 2040 (0.34%)
occurrences (all)	0	1	7
Foot fracture			
subjects affected / exposed	5 / 2014 (0.25%)	12 / 2014 (0.60%)	15 / 2040 (0.74%)
occurrences (all)	5	12	16
Foreign body			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Foreign body in eye			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Fracture			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences (all)	1	5	1
Fractured ischium			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	2	4	2
Fractured sacrum			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal injury			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Frostbite			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Gingival injury			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Hand fracture			
subjects affected / exposed	5 / 2014 (0.25%)	17 / 2014 (0.84%)	8 / 2040 (0.39%)

occurrences (all)	5	17	8
Head injury			
subjects affected / exposed	11 / 2014 (0.55%)	26 / 2014 (1.29%)	17 / 2040 (0.83%)
occurrences (all)	11	28	18
Heart injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Humerus fracture			
subjects affected / exposed	7 / 2014 (0.35%)	19 / 2014 (0.94%)	18 / 2040 (0.88%)
occurrences (all)	7	19	18
Iliotibial band syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Ilium fracture			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	3	3	0
Incisional hernia			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Injury			
subjects affected / exposed	5 / 2014 (0.25%)	9 / 2014 (0.45%)	5 / 2040 (0.25%)
occurrences (all)	5	10	5
Jaw fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	7 / 2040 (0.34%)
occurrences (all)	3	6	8
Joint injury			
subjects affected / exposed	16 / 2014 (0.79%)	50 / 2014 (2.48%)	43 / 2040 (2.11%)
occurrences (all)	16	63	56
Laceration			
subjects affected / exposed	14 / 2014 (0.70%)	24 / 2014 (1.19%)	19 / 2040 (0.93%)
occurrences (all)	14	25	22
Ligament injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences (all)	0	1	0
Ligament rupture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Ligament sprain			
subjects affected / exposed	13 / 2014 (0.65%)	32 / 2014 (1.59%)	33 / 2040 (1.62%)
occurrences (all)	15	35	34
Limb crushing injury			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Limb injury			
subjects affected / exposed	24 / 2014 (1.19%)	54 / 2014 (2.68%)	58 / 2040 (2.84%)
occurrences (all)	25	71	72
Lumbar vertebral fracture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	2	2
Lip injury			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Meniscus injury			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences (all)	1	2	4
Multiple injuries			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Muscle injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	0	1	4
Muscle rupture			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Muscle strain			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	9 / 2040 (0.44%)
occurrences (all)	3	7	11
Nasal injury			
subjects affected / exposed	3 / 2014 (0.15%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)

occurrences (all)	3	3	3
Neck injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	0	1	3
Overdose			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	4	5	1
Patella fracture			
subjects affected / exposed	1 / 2014 (0.05%)	6 / 2014 (0.30%)	7 / 2040 (0.34%)
occurrences (all)	1	7	7
Pelvic organ injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Perineal injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Periorbital haematoma			
subjects affected / exposed	3 / 2014 (0.15%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	3	3	3
Periorbital haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Peripheral nerve injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Post concussion syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Post procedural complication			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	1	3	2
Post procedural fistula			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
Post procedural oedema subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Post procedural hypothyroidism subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Post procedural swelling subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Post-traumatic neck syndrome subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Post-traumatic pain subjects affected / exposed	7 / 2014 (0.35%)	8 / 2014 (0.40%)	3 / 2040 (0.15%)
occurrences (all)	7	8	3
Postoperative fever subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Procedural complication subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Procedural pain subjects affected / exposed	5 / 2014 (0.25%)	10 / 2014 (0.50%)	13 / 2040 (0.64%)
occurrences (all)	5	11	16
Procedural nausea subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pubis fracture subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	2 / 2040 (0.10%)
occurrences (all)	2	6	2
Radiation associated pain subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Radiation leukopenia subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
Radius fracture			
subjects affected / exposed	28 / 2014 (1.39%)	50 / 2014 (2.48%)	48 / 2040 (2.35%)
occurrences (all)	29	51	49
Respiratory fume inhalation disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Road traffic accident			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3
Rib fracture			
subjects affected / exposed	10 / 2014 (0.50%)	25 / 2014 (1.24%)	19 / 2040 (0.93%)
occurrences (all)	10	32	22
Scar			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Seroma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Scratch			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Skin abrasion			
subjects affected / exposed	7 / 2014 (0.35%)	23 / 2014 (1.14%)	19 / 2040 (0.93%)
occurrences (all)	11	35	23
Skeletal injury			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Skin injury			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	3	4	3
Skin wound			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Skull fracture			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)



occurrences (all)	1	1	0
Soft tissue injury			
subjects affected / exposed	13 / 2014 (0.65%)	27 / 2014 (1.34%)	37 / 2040 (1.81%)
occurrences (all)	14	34	48
Spinal column injury			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	1	4	6
Spinal compression fracture			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Spinal fracture			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	6 / 2040 (0.29%)
occurrences (all)	1	5	6
Sternal fracture			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Stoma obstruction			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Subcutaneous haematoma			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Subdural haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	3	0
Sunburn			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Synovial rupture			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Tendon injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tendon rupture			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)

occurrences (all)	2	3	5
Thoracic vertebral fracture subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tibia fracture subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	2	4	3
Thermal burn subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	12 / 2040 (0.59%)
occurrences (all)	3	8	13
Tongue injury subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Tooth injury subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	4	0
Tooth avulsion subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Tooth fracture subjects affected / exposed	4 / 2014 (0.20%)	11 / 2014 (0.55%)	11 / 2040 (0.54%)
occurrences (all)	5	13	13
Toxicity to various agents subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Transfusion reaction subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Traumatic haematoma subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	0	2	4
Traumatic haemothorax subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Traumatic lung injury subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
Vaccination complication			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Ulna fracture			
subjects affected / exposed	17 / 2014 (0.84%)	29 / 2014 (1.44%)	27 / 2040 (1.32%)
occurrences (all)	17	29	27
Vaginal laceration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vascular injury			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Wound haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vascular pseudoaneurysm			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Wound			
subjects affected / exposed	6 / 2014 (0.30%)	27 / 2014 (1.34%)	25 / 2040 (1.23%)
occurrences (all)	6	31	25
Wound secretion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Wrist fracture			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	5 / 2040 (0.25%)
occurrences (all)	0	0	5
Anticoagulation drug level above therapeutic			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0

Aortic bruit			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	0	2	2
Aspiration joint			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	1	4	5
Blood bilirubin increased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Blood calcium increased			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	2	3	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Blood cholesterol abnormal			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Blood cholesterol increased			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Blood chloride decreased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Blood creatine increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Blood glucose abnormal			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2

Blood glucose increased subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	4 / 2014 (0.20%) 4	3 / 2040 (0.15%) 3
Blood folate decreased subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Blood magnesium decreased subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Blood potassium abnormal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Blood potassium decreased subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Blood pressure abnormal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	3 / 2040 (0.15%) 3
Blood potassium increased subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Blood pressure ambulatory subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Blood pressure decreased subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	3 / 2014 (0.15%) 3	0 / 2040 (0.00%) 0
Blood pressure diastolic increased subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Blood sodium decreased subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Blood thyroid stimulating hormone increased subjects affected / exposed	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1

occurrences (all)	0	0	1
Blood pressure increased subjects affected / exposed	10 / 2014 (0.50%)	20 / 2014 (0.99%)	17 / 2040 (0.83%)
occurrences (all)	12	24	19
Blood urea increased subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Blood triglycerides increased subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Body mass index increased subjects affected / exposed	6 / 2014 (0.30%)	12 / 2014 (0.60%)	7 / 2040 (0.34%)
occurrences (all)	6	13	11
Blood uric acid increased subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Body height decreased subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	4 / 2040 (0.20%)
occurrences (all)	2	4	4
Bone density abnormal subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Body temperature increased subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	0	1	3
Bone density decreased subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Brain scan abnormal subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Carcinoembryonic antigen increased subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Cardiac function test abnormal subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Computerised tomogram head abnormal			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Chest X-ray abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Cardiac murmur			
subjects affected / exposed	4 / 2014 (0.20%)	8 / 2014 (0.40%)	5 / 2040 (0.25%)
occurrences (all)	4	8	5
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Fibrin D dimer increased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Escherichia test positive			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Glomerular filtration rate decreased			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences (all)	1	3	6

Haemoglobin			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Haemoglobin abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	0	1	4
Haemoglobin increased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Heart rate increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences (all)	0	0	5
Heart rate irregular			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	3
Hepatic enzyme increased			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences (all)	1	2	4
Inflammatory marker increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
International normalised ratio decreased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Intestinal transit time decreased			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Intraocular pressure increased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)



occurrences (all)	0	1	1
Klebsiella test positive			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Liver function test abnormal			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Liver function test increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Low density lipoprotein increased			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Lymphocyte count increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	2
Mycoplasma test positive			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Monocyte count increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	3
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Occult blood positive			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Occult blood			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Oxygen saturation decreased			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Red blood cell sedimentation rate increased			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Renal function test abnormal			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Staphylococcus test positive			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Thyroxine increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	1	4	1
Ultrasound liver abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ultrasound uterus abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Urine analysis abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Urine output increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vitamin D decreased			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0

Weight decreased subjects affected / exposed occurrences (all)	22 / 2014 (1.09%) 23	49 / 2014 (2.43%) 53	33 / 2040 (1.62%) 36
Weight increased subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	6 / 2014 (0.30%) 6	3 / 2040 (0.15%) 3
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 2
Cardiac disorders			
Acute coronary syndrome subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Acute myocardial infarction subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Angina pectoris subjects affected / exposed occurrences (all)	6 / 2014 (0.30%) 7	12 / 2014 (0.60%) 13	12 / 2040 (0.59%) 13
Angina unstable subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Aortic valve calcification subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Aortic valve disease mixed subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Aortic valve incompetence subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	7 / 2014 (0.35%) 8	15 / 2040 (0.74%) 15
Aortic valve sclerosis subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)

occurrences (all)	1	3	0
Aortic valve stenosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	3
Arrhythmia			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences (all)	3	7	5
Arrhythmia supraventricular			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	2	3	3
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	5 / 2040 (0.25%)
occurrences (all)	1	3	5
Atrial fibrillation			
subjects affected / exposed	10 / 2014 (0.50%)	27 / 2014 (1.34%)	29 / 2040 (1.42%)
occurrences (all)	11	29	33
Atrial flutter			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Atrial tachycardia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Atrioventricular block			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Atrioventricular block complete			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Atrioventricular block first degree			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Bradycardia			
subjects affected / exposed	4 / 2014 (0.20%)	10 / 2014 (0.50%)	5 / 2040 (0.25%)

occurrences (all)	4	11	5
Bundle branch block			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Bundle branch block left			
subjects affected / exposed	4 / 2014 (0.20%)	7 / 2014 (0.35%)	6 / 2040 (0.29%)
occurrences (all)	4	7	6
Bundle branch block right			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Cardiac discomfort			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cardiac failure			
subjects affected / exposed	12 / 2014 (0.60%)	25 / 2014 (1.24%)	22 / 2040 (1.08%)
occurrences (all)	12	27	23
Cardiac failure chronic			
subjects affected / exposed	7 / 2014 (0.35%)	15 / 2014 (0.74%)	12 / 2040 (0.59%)
occurrences (all)	8	16	12
Cardiac failure congestive			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	6 / 2040 (0.29%)
occurrences (all)	1	5	6
Cardiac hypertrophy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Cardiac septal hypertrophy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Cardiac valve disease			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Cardiac valve sclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Cardiomegaly			
subjects affected / exposed	1 / 2014 (0.05%)	8 / 2014 (0.40%)	9 / 2040 (0.44%)

occurrences (all)	1	8	9
Cardiomyopathy			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	0	3	3
Cardiovascular disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	2
Cardiovascular insufficiency			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Conduction disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Congestive cardiomyopathy			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Coronary artery disease			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	9 / 2040 (0.44%)
occurrences (all)	4	9	9
Coronary artery stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Defect conduction intraventricular			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Degenerative aortic valve disease			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Degenerative mitral valve disease			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Diastolic dysfunction			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	1	4	1
Dilatation atrial			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)

occurrences (all)	0	1	4
Dilatation ventricular			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Extrasystoles			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	6 / 2040 (0.29%)
occurrences (all)	1	2	7
Heart valve incompetence			
subjects affected / exposed	1 / 2014 (0.05%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences (all)	1	6	4
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Hypertensive heart disease			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	6 / 2040 (0.29%)
occurrences (all)	0	1	6
Left atrial dilatation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Left atrial enlargement			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Left atrial hypertrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Left ventricular dilatation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Left ventricular dysfunction			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	8 / 2040 (0.39%)
occurrences (all)	1	3	8
Left ventricular failure			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Left ventricular hypertrophy			
subjects affected / exposed	0 / 2014 (0.00%)	4 / 2014 (0.20%)	4 / 2040 (0.20%)

occurrences (all)	0	4	4
Mitral valve disease			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Mitral valve incompetence			
subjects affected / exposed	5 / 2014 (0.25%)	24 / 2014 (1.19%)	26 / 2040 (1.27%)
occurrences (all)	6	26	26
Mitral valve prolapse			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	0 / 2040 (0.00%)
occurrences (all)	3	4	0
Mitral valve sclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Mitral valve stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Myocardial fibrosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Myocardial infarction			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Myocardial ischaemia			
subjects affected / exposed	3 / 2014 (0.15%)	10 / 2014 (0.50%)	14 / 2040 (0.69%)
occurrences (all)	3	10	15
Nodal rhythm			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Palpitations			
subjects affected / exposed	7 / 2014 (0.35%)	15 / 2014 (0.74%)	13 / 2040 (0.64%)
occurrences (all)	8	16	14
Pericardial effusion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	5 / 2040 (0.25%)
occurrences (all)	0	0	5
Postinfarction angina			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)



occurrences (all)	0	1	0
Pulmonary valve incompetence subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Right atrial dilatation subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Right ventricular failure subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Sinus bradycardia subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences (all)	3	3	5
Sinus node dysfunction subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Sinus tachycardia subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Supraventricular extrasystoles subjects affected / exposed	4 / 2014 (0.20%)	8 / 2014 (0.40%)	8 / 2040 (0.39%)
occurrences (all)	4	8	8
Supraventricular tachycardia subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Systolic dysfunction subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Tachyarrhythmia subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tachycardia subjects affected / exposed	5 / 2014 (0.25%)	8 / 2014 (0.40%)	8 / 2040 (0.39%)
occurrences (all)	5	8	10
Tricuspid valve incompetence subjects affected / exposed	4 / 2014 (0.20%)	22 / 2014 (1.09%)	13 / 2040 (0.64%)

occurrences (all)	4	22	13
Ventricular arrhythmia			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	2	2	5
Ventricular extrasystoles			
subjects affected / exposed	6 / 2014 (0.30%)	7 / 2014 (0.35%)	7 / 2040 (0.34%)
occurrences (all)	6	7	7
Ventricular fibrillation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ventricular tachycardia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Biliary hamartoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Congenital cerebrovascular anomaly			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Congenital cystic kidney disease			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Congenital hypercoagulation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Corneal dystrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Hypertrophic cardiomyopathy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Muscular dystrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Odontogenic cyst subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Thalassaemia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Tuberous sclerosis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Vertebral artery hypoplasia subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
<b>Blood and lymphatic system disorders</b>			
Anaemia subjects affected / exposed occurrences (all)	49 / 2014 (2.43%) 53	113 / 2014 (5.61%) 128	84 / 2040 (4.12%) 100
Anaemia megaloblastic subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Anaemia of chronic disease subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Anaemia vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Anaemia vitamin B6 deficiency subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Bicytopenia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Eosinophilia subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	4 / 2014 (0.20%) 4	0 / 2040 (0.00%) 0
Granulocytopenia subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences (all)	1	1	0
Haemoconcentration			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Haemorrhagic anaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Hyperchromic anaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hypochromic anaemia			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Increased tendency to bruise			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Iron deficiency anaemia			
subjects affected / exposed	4 / 2014 (0.20%)	12 / 2014 (0.60%)	9 / 2040 (0.44%)
occurrences (all)	4	14	9
Leukocytosis			
subjects affected / exposed	4 / 2014 (0.20%)	7 / 2014 (0.35%)	5 / 2040 (0.25%)
occurrences (all)	4	7	5
Leukopenia			
subjects affected / exposed	4 / 2014 (0.20%)	7 / 2014 (0.35%)	8 / 2040 (0.39%)
occurrences (all)	4	8	10
Lymph node pain			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	1	2	3
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Lymphocytosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)

occurrences (all)	1	1	2
Lymphopenia			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	2	4	2
Microcytic anaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Neutropenia			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	7 / 2040 (0.34%)
occurrences (all)	1	4	7
Neutrophilia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	1	1	4
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	4 / 2040 (0.20%)
occurrences (all)	1	5	4
Pancytopenia			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Pernicious anaemia			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	1	3	1
Purpura non-thrombocytopenic			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Retroperitoneal lymphadenopathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	3 / 2014 (0.15%)	13 / 2014 (0.65%)	12 / 2040 (0.59%)
occurrences (all)	4	16	14
Thrombocytosis			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	8 / 2040 (0.39%)
occurrences (all)	2	3	9
Nervous system disorders			

Amnesia			
subjects affected / exposed	5 / 2014 (0.25%)	10 / 2014 (0.50%)	10 / 2040 (0.49%)
occurrences (all)	5	11	11
Amnestic disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	2
Amputation stump pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Anticholinergic syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Aphasia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Ataxia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Balance disorder			
subjects affected / exposed	6 / 2014 (0.30%)	9 / 2014 (0.45%)	7 / 2040 (0.34%)
occurrences (all)	6	10	7
Autonomic nervous system imbalance			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Aura			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Brain oedema			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Brain injury			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	1	3	3
Carotid artery stenosis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3

Carotid arteriosclerosis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	6 / 2014 (0.30%) 6	5 / 2040 (0.25%) 6
Burning sensation subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 3	6 / 2014 (0.30%) 7	4 / 2040 (0.20%) 4
Carpal tunnel syndrome subjects affected / exposed occurrences (all)	8 / 2014 (0.40%) 8	18 / 2014 (0.89%) 18	13 / 2040 (0.64%) 13
Central nervous system necrosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Central nervous system lesion subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Cerebellar atrophy subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Cerebral amyloid angiopathy subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Cerebral artery embolism subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Cerebral arteriosclerosis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	4 / 2014 (0.20%) 4	8 / 2040 (0.39%) 8
Cerebral atrophy subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	5 / 2014 (0.25%) 5	7 / 2040 (0.34%) 7
Cerebral calcification subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Cerebral artery stenosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1

Cerebral disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Cerebral circulatory failure			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cerebral haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Cerebral hypoperfusion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cerebral haematoma			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Cerebral ischaemia			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	2	4	3
Cerebral infarction			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cerebral ventricle dilatation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Cerebral microangiopathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Cerebroscclerosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cerebrovascular accident			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)



occurrences (all)	0	3	3
Cerebrovascular insufficiency subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Cerebrovascular disorder subjects affected / exposed	3 / 2014 (0.15%)	5 / 2014 (0.25%)	10 / 2040 (0.49%)
occurrences (all)	3	5	10
Cervical radiculopathy subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	2	4	3
Cervicobrachial syndrome subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Circadian rhythm sleep disorder subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cognitive disorder subjects affected / exposed	2 / 2014 (0.10%)	8 / 2014 (0.40%)	8 / 2040 (0.39%)
occurrences (all)	2	8	8
Coma subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Dementia subjects affected / exposed	4 / 2014 (0.20%)	14 / 2014 (0.70%)	19 / 2040 (0.93%)
occurrences (all)	4	14	19
Dementia Alzheimer's type subjects affected / exposed	3 / 2014 (0.15%)	11 / 2014 (0.55%)	8 / 2040 (0.39%)
occurrences (all)	3	12	8
Diabetic neuropathy subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Disturbance in attention subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Dizziness subjects affected / exposed	80 / 2014 (3.97%)	152 / 2014 (7.55%)	149 / 2040 (7.30%)

occurrences (all)	91	193	190
Dizziness postural			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	7 / 2040 (0.34%)
occurrences (all)	1	3	8
Dysaesthesia			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	2	3	3
Dysarthria			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	1	3	1
Dysgeusia			
subjects affected / exposed	5 / 2014 (0.25%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences (all)	5	5	1
Dyskinesia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Encephalopathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Encephalomalacia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Epidural lipomatosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Essential tremor			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	2	3	0
Epilepsy			
subjects affected / exposed	4 / 2014 (0.20%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences (all)	4	5	1
Facial neuralgia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Facial paralysis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)

occurrences (all)	1	2	4
<b>Gliositis</b>			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
<b>Haemorrhagic stroke</b>			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
<b>Headache</b>			
subjects affected / exposed	110 / 2014 (5.46%)	190 / 2014 (9.43%)	163 / 2040 (7.99%)
occurrences (all)	122	241	210
<b>Hydrocephalus</b>			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
<b>Hemiparesis</b>			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	1	2	5
<b>Hypersomnia</b>			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
<b>Hypoaesthesia</b>			
subjects affected / exposed	14 / 2014 (0.70%)	26 / 2014 (1.29%)	25 / 2040 (1.23%)
occurrences (all)	16	32	27
<b>Hypertensive encephalopathy</b>			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
<b>Hypotonia</b>			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
<b>Hypokinesia</b>			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
<b>IIIrd nerve paralysis</b>			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
<b>Incoherent</b>			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
Intention tremor			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Intercostal neuralgia			
subjects affected / exposed	1 / 2014 (0.05%)	7 / 2014 (0.35%)	2 / 2040 (0.10%)
occurrences (all)	1	8	2
Intracranial aneurysm			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	2	2	2
Intracranial haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ischaemic stroke			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Lacunar infarction			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	1	4	3
Lethargy			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	0	2	2
Lacunar stroke			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Loss of consciousness			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	9 / 2040 (0.44%)
occurrences (all)	1	5	10
Leukoencephalopathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Lumbar radiculopathy			
subjects affected / exposed	1 / 2014 (0.05%)	8 / 2014 (0.40%)	7 / 2040 (0.34%)
occurrences (all)	1	12	7
Memory impairment			
subjects affected / exposed	10 / 2014 (0.50%)	31 / 2014 (1.54%)	34 / 2040 (1.67%)

occurrences (all)	10	33	36
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Migraine			
subjects affected / exposed	11 / 2014 (0.55%)	13 / 2014 (0.65%)	5 / 2040 (0.25%)
occurrences (all)	13	20	5
Metabolic encephalopathy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Monoparesis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Multiple sclerosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Muscle contractions involuntary			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	2
Muscle spasticity			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Myoclonus			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Nerve root compression			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	1	3	3
Nervous system disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Nerve compression			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	7 / 2014 (0.35%)	9 / 2014 (0.45%)	10 / 2040 (0.49%)

occurrences (all)	8	12	10
Neuralgic amyotrophy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Neuritis			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	0 / 2040 (0.00%)
occurrences (all)	3	4	0
Neurodegenerative disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	6 / 2040 (0.29%)
occurrences (all)	2	5	7
Nystagmus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Occipital neuralgia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Notalgia paraesthetica			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Paresis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Parkinson's disease			
subjects affected / exposed	1 / 2014 (0.05%)	7 / 2014 (0.35%)	11 / 2040 (0.54%)
occurrences (all)	1	8	12
Paraesthesia			
subjects affected / exposed	34 / 2014 (1.69%)	53 / 2014 (2.63%)	41 / 2040 (2.01%)
occurrences (all)	36	58	45
Parkinsonism			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	4 / 2040 (0.20%)
occurrences (all)	2	4	4
Partial seizures			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)

occurrences (all)	1	1	4
Parosmia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Peripheral nerve lesion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Petit mal epilepsy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Polyneuropathy			
subjects affected / exposed	3 / 2014 (0.15%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	3	3	4
Post herpetic neuralgia			
subjects affected / exposed	2 / 2014 (0.10%)	8 / 2014 (0.40%)	5 / 2040 (0.25%)
occurrences (all)	2	8	5
Polyneuropathy alcoholic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Poor quality sleep			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)

occurrences (all)	1	4	5
Post-traumatic headache			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Rabbit syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Radicular pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Radicular syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Radiculopathy			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences (all)	1	5	2
Restless legs syndrome			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	1	4	2
Sciatica			
subjects affected / exposed	22 / 2014 (1.09%)	51 / 2014 (2.53%)	48 / 2040 (2.35%)
occurrences (all)	23	57	57
Seizure			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	8
Senile dementia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Seizure anoxic			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Sinus headache			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Sensory disturbance			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)



occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	7 / 2014 (0.35%)	8 / 2014 (0.40%)	5 / 2040 (0.25%)
occurrences (all)	9	11	5
Speech disorder			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	1	3	2
Spinal claudication			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Spinal cord disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Spinal meningeal cyst			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Subdural effusion			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Stroke in evolution			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	11 / 2014 (0.55%)	23 / 2014 (1.14%)	32 / 2040 (1.57%)
occurrences (all)	11	24	41
Tension headache			
subjects affected / exposed	5 / 2014 (0.25%)	8 / 2014 (0.40%)	10 / 2040 (0.49%)
occurrences (all)	6	9	11
Tremor			
subjects affected / exposed	5 / 2014 (0.25%)	16 / 2014 (0.79%)	15 / 2040 (0.74%)
occurrences (all)	5	16	15
Transient ischaemic attack			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	7 / 2040 (0.34%)
occurrences (all)	0	1	8
Trigeminal nerve disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences (all)	0	1	0
Trigeminal neuritis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Trigeminal neuralgia			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	1	3	2
Ulnar neuritis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
VIth nerve disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Unresponsive to stimuli			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vascular dementia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Vascular encephalopathy			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Vertebral artery stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vertebrobasilar insufficiency			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	1	2	5
Vocal cord paresis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
White matter lesion			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Eye disorders			

Age-related macular degeneration subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	5 / 2040 (0.25%) 5
Amblyopia subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Amaurosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Anisometropia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Asthenopia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Anterior capsule contraction subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Astigmatism subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Blepharitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 3
Blepharochalasis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 3	0 / 2040 (0.00%) 0
Blepharospasm subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Cataract subjects affected / exposed occurrences (all)	32 / 2014 (1.59%) 38	97 / 2014 (4.82%) 121	105 / 2040 (5.15%) 128
Chalazion subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	3 / 2040 (0.15%) 4

Cataract nuclear subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	8 / 2014 (0.40%) 8	12 / 2040 (0.59%) 12
Conjunctival oedema subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Conjunctival irritation subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Corneal degeneration subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Conjunctivitis allergic subjects affected / exposed occurrences (all)	8 / 2014 (0.40%) 8	12 / 2014 (0.60%) 12	12 / 2040 (0.59%) 12
Corneal disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Corneal erosion subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Corneal opacity subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Cystoid macular oedema subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Dacryostenosis acquired subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Diabetic retinopathy subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0

Dry eye			
subjects affected / exposed	8 / 2014 (0.40%)	15 / 2014 (0.74%)	17 / 2040 (0.83%)
occurrences (all)	8	15	20
Diplopia			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	1	2	3
Eczema eyelids			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Endocrine ophthalmopathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Episcleritis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Exfoliation glaucoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Eye allergy			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	2	3	1
Eye degenerative disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	2	2
Eye inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Eye haemorrhage			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3
Eye irritation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	0	1	4
Eye pain			
subjects affected / exposed	4 / 2014 (0.20%)	11 / 2014 (0.55%)	8 / 2040 (0.39%)
occurrences (all)	5	15	8

Eye pruritus			
subjects affected / exposed	1 / 2014 (0.05%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	1	6	3
Eye swelling			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Eye ulcer			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Eyelid cyst			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Eyelid dermatochalasis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Eyelid disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Eyelid pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Eyelid ptosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Foreign body sensation in eyes			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Glaucoma			
subjects affected / exposed	8 / 2014 (0.40%)	24 / 2014 (1.19%)	25 / 2040 (1.23%)
occurrences (all)	8	25	25
Hypermetropia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Iridocyclitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Iritis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Keratitis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Keratopathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Lacrimonal disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Lacrimonal structural disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Lacrimation decreased			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Lacrimation increased			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences (all)	3	6	5
Macular degeneration			
subjects affected / exposed	1 / 2014 (0.05%)	13 / 2014 (0.65%)	10 / 2040 (0.49%)
occurrences (all)	1	13	11
Macular fibrosis			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Macular hole			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Maculopathy			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	2	3	0

Myopia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Narrow anterior chamber angle			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Ocular discomfort			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Ocular hyperaemia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Open angle glaucoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Optic disc disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Posterior capsule opacification			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	0 / 2040 (0.00%)
occurrences (all)	2	6	0
Photopsia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Presbyopia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pterygium			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Refraction disorder			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1



Retinal degeneration subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Retinal detachment subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 3	2 / 2040 (0.10%) 2
Retinal haemorrhage subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	3 / 2040 (0.15%) 3
Retinal vascular disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Retinal tear subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Retinal vascular occlusion subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Retinal vein occlusion subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Retinal vein thrombosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Retinopathy hypertensive subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Retinopathy subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Strabismus subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Ulcerative keratitis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0

Trichiasis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Uveitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Vision blurred			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	11 / 2040 (0.54%)
occurrences (all)	2	5	12
Visual acuity reduced			
subjects affected / exposed	2 / 2014 (0.10%)	8 / 2014 (0.40%)	3 / 2040 (0.15%)
occurrences (all)	2	8	3
Visual impairment			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	9 / 2040 (0.44%)
occurrences (all)	1	4	9
Vitreous adhesions			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Vitreous degeneration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vitreous detachment			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Vitreous disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vitreous floaters			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	2
Vitreous haemorrhage			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	1	2	6
Xerophthalmia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0

Ear and labyrinth disorders			
Acute vestibular syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Cerumen impaction			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	11 / 2040 (0.54%)
occurrences (all)	5	10	12
Cupulolithiasis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Deafness bilateral			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Ear canal erythema			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Ear discomfort			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ear disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	14 / 2040 (0.69%)
occurrences (all)	4	11	15
Ear pruritus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Excessive cerumen production			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	5 / 2040 (0.25%)
occurrences (all)	0	1	5
Hypoacusis			
subjects affected / exposed	17 / 2014 (0.84%)	34 / 2014 (1.69%)	26 / 2040 (1.27%)
occurrences (all)	17	34	29
Inner ear disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)

occurrences (all)	1	1	3
Meniere's disease			
subjects affected / exposed	4 / 2014 (0.20%)	5 / 2014 (0.25%)	3 / 2040 (0.15%)
occurrences (all)	4	5	3
Motion sickness			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Neurosensory hypoacusis			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Presbycusis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Tinnitus			
subjects affected / exposed	10 / 2014 (0.50%)	21 / 2014 (1.04%)	15 / 2040 (0.74%)
occurrences (all)	10	22	17
Tympanic membrane perforation			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	1	4	2
Vertigo			
subjects affected / exposed	36 / 2014 (1.79%)	66 / 2014 (3.28%)	82 / 2040 (4.02%)
occurrences (all)	38	78	106
Vertigo positional			
subjects affected / exposed	7 / 2014 (0.35%)	10 / 2014 (0.50%)	9 / 2040 (0.44%)
occurrences (all)	7	10	10
Vestibular ataxia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Vestibular disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	9 / 2014 (0.45%)	15 / 2014 (0.74%)	13 / 2040 (0.64%)
occurrences (all)	11	17	14
Abdominal adhesions			

subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	15 / 2014 (0.74%)	23 / 2014 (1.14%)	17 / 2040 (0.83%)
occurrences (all)	15	24	18
Abdominal hernia			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	1 / 2040 (0.05%)
occurrences (all)	2	6	1
Abdominal mass			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	42 / 2014 (2.09%)	84 / 2014 (4.17%)	66 / 2040 (3.24%)
occurrences (all)	47	98	74
Abdominal pain lower			
subjects affected / exposed	8 / 2014 (0.40%)	14 / 2014 (0.70%)	12 / 2040 (0.59%)
occurrences (all)	8	17	12
Abdominal pain upper			
subjects affected / exposed	63 / 2014 (3.13%)	109 / 2014 (5.41%)	101 / 2040 (4.95%)
occurrences (all)	72	129	121
Abdominal rigidity			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Abdominal symptom			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Abnormal faeces			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Acid peptic disease			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Anal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Anal incontinence			

subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	2	3	3
Anal prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Anal pruritus			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Anal sphincter atony			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Anal ulcer			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Anorectal disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Anorectal varices			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Aphthous ulcer			
subjects affected / exposed	3 / 2014 (0.15%)	3 / 2014 (0.15%)	10 / 2040 (0.49%)
occurrences (all)	3	3	12
Apical granuloma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Aptyalism			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Barrett's oesophagus			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Breath odour			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Change of bowel habit			

subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	2 / 2040 (0.10%)
occurrences (all)	2	5	2
Cheilitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	2
Chronic gastritis			
subjects affected / exposed	15 / 2014 (0.74%)	30 / 2014 (1.49%)	20 / 2040 (0.98%)
occurrences (all)	15	30	21
Coeliac disease			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Colitis			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	2	4	5
Colitis erosive			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Colitis psychogenic			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Colitis ischaemic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Colitis ulcerative			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	92 / 2014 (4.57%)	133 / 2014 (6.60%)	120 / 2040 (5.88%)
occurrences (all)	99	155	133
Dental caries			
subjects affected / exposed	11 / 2014 (0.55%)	33 / 2014 (1.64%)	27 / 2040 (1.32%)
occurrences (all)	12	42	32
Diaphragmatic hernia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			

subjects affected / exposed	93 / 2014 (4.62%)	168 / 2014 (8.34%)	165 / 2040 (8.09%)
occurrences (all)	119	236	204
Diverticulum			
subjects affected / exposed	0 / 2014 (0.00%)	5 / 2014 (0.25%)	7 / 2040 (0.34%)
occurrences (all)	0	5	7
Diverticulum intestinal			
subjects affected / exposed	8 / 2014 (0.40%)	19 / 2014 (0.94%)	19 / 2040 (0.93%)
occurrences (all)	8	19	21
Dry mouth			
subjects affected / exposed	7 / 2014 (0.35%)	13 / 2014 (0.65%)	14 / 2040 (0.69%)
occurrences (all)	7	13	14
Duodenal polyp			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Duodenitis			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	3 / 2040 (0.15%)
occurrences (all)	2	5	3
Duodenal ulcer			
subjects affected / exposed	0 / 2014 (0.00%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	0	4	1
Duodenogastric reflux			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	0	3	1
Dyspepsia			
subjects affected / exposed	50 / 2014 (2.48%)	82 / 2014 (4.07%)	92 / 2040 (4.51%)
occurrences (all)	53	98	103
Dysphagia			
subjects affected / exposed	1 / 2014 (0.05%)	6 / 2014 (0.30%)	9 / 2040 (0.44%)
occurrences (all)	1	6	9
Enteritis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Enterocolitis			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	2	4	0
Epigastric discomfort			



subjects affected / exposed	3 / 2014 (0.15%)	7 / 2014 (0.35%)	6 / 2040 (0.29%)
occurrences (all)	4	8	6
Erosive oesophagitis			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	2	4	2
Erosive duodenitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Eructation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	3
Faeces discoloured			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Food poisoning			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	6 / 2040 (0.29%)
occurrences (all)	3	7	6
Flatulence			
subjects affected / exposed	14 / 2014 (0.70%)	16 / 2014 (0.79%)	13 / 2040 (0.64%)
occurrences (all)	15	19	13
Frequent bowel movements			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Gastric disorder			
subjects affected / exposed	4 / 2014 (0.20%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences (all)	4	6	4
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Gastric mucosa erythema			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	2
Gastric mucosal hypertrophy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Gastric polyps			

subjects affected / exposed	4 / 2014 (0.20%)	10 / 2014 (0.50%)	1 / 2040 (0.05%)
occurrences (all)	4	10	1
Gastric ulcer			
subjects affected / exposed	2 / 2014 (0.10%)	8 / 2014 (0.40%)	9 / 2040 (0.44%)
occurrences (all)	2	8	10
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Gastritis			
subjects affected / exposed	59 / 2014 (2.93%)	101 / 2014 (5.01%)	92 / 2040 (4.51%)
occurrences (all)	67	123	118
Gastritis erosive			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	6 / 2040 (0.29%)
occurrences (all)	1	5	6
Gastritis haemorrhagic			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Gastroduodenal ulcer			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Gastroduodenitis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Gastrointestinal angiectasia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	6 / 2014 (0.30%)	10 / 2014 (0.50%)	2 / 2040 (0.10%)
occurrences (all)	6	12	2
Gastrointestinal fistula			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences (all)	0	0	4
Gastrointestinal hypermotility			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal mucosal disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal obstruction			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal tract irritation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal wall thickening			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	36 / 2014 (1.79%)	58 / 2014 (2.88%)	64 / 2040 (3.14%)
occurrences (all)	39	65	72
Gingival atrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrooesophageal sphincter insufficiency			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0

Gingival bleeding subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Gingival disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Gingival erythema subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Gingival hypertrophy subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Gingival pain subjects affected / exposed occurrences (all)	9 / 2014 (0.45%) 9	14 / 2014 (0.70%) 15	6 / 2040 (0.29%) 6
Gingival recession subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Gingival swelling subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	3 / 2040 (0.15%) 3
Glossitis subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Haematemesis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Haematochezia subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	4 / 2014 (0.20%) 4	6 / 2040 (0.29%) 6
Haemorrhagic erosive gastritis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Haemorrhoidal haemorrhage subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	5 / 2040 (0.25%) 5

Haemorrhoids			
subjects affected / exposed	19 / 2014 (0.94%)	37 / 2014 (1.84%)	32 / 2040 (1.57%)
occurrences (all)	19	41	32
Hernial eventration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hiatus hernia			
subjects affected / exposed	15 / 2014 (0.74%)	30 / 2014 (1.49%)	24 / 2040 (1.18%)
occurrences (all)	15	31	24
Hyperchlorhydria			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Hypoaesthesia oral			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Hypoaesthesia teeth			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ileus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Inguinal hernia			
subjects affected / exposed	3 / 2014 (0.15%)	7 / 2014 (0.35%)	1 / 2040 (0.05%)
occurrences (all)	4	8	1
Intestinal metaplasia			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	0 / 2040 (0.00%)
occurrences (all)	2	5	0
Intestinal polyp			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Irritable bowel syndrome			
subjects affected / exposed	15 / 2014 (0.74%)	32 / 2014 (1.59%)	17 / 2040 (0.83%)
occurrences (all)	20	42	20

Large intestinal stenosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Large intestine polyp subjects affected / exposed occurrences (all)	7 / 2014 (0.35%) 7	14 / 2014 (0.70%) 14	16 / 2040 (0.78%) 16
Lip discolouration subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Lip haematoma subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Lip swelling subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Loose tooth subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	6 / 2014 (0.30%) 6	8 / 2040 (0.39%) 8
Lower gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 4	3 / 2014 (0.15%) 4	1 / 2040 (0.05%) 1
Malabsorption subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Melaena subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Mouth swelling subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Mouth ulceration subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	5 / 2040 (0.25%) 5
Nausea subjects affected / exposed occurrences (all)	32 / 2014 (1.59%) 33	47 / 2014 (2.33%) 53	63 / 2040 (3.09%) 80

Noninfective gingivitis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Noninfective sialoadenitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Obstruction gastric subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Odynophagia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Oesophageal disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Oesophageal polyp subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Oesophageal stenosis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Oesophageal ulcer subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Oesophagitis subjects affected / exposed occurrences (all)	7 / 2014 (0.35%) 7	8 / 2014 (0.40%) 8	6 / 2040 (0.29%) 7
Oral contusion subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Oral discomfort subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Oral disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 3

Oral mucosal discolouration subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Pancreatic cyst subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Pancreatic disorder subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Pancreatitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Pancreatitis chronic subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	4 / 2014 (0.20%) 4	0 / 2040 (0.00%) 0
Peptic ulcer subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	7 / 2014 (0.35%) 7	3 / 2040 (0.15%) 3
Periodontal disease subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	2 / 2040 (0.10%) 2
Periodontal inflammation subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Peritoneal adhesions subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Pharyngo-oesophageal diverticulum subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Presbyoesophagus subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Proctalgia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1



Proctitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	6 / 2040 (0.29%)
occurrences (all)	2	5	7
Rectal polyp			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Rectal prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Reflux gastritis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Salivary gland calculus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Salivary gland enlargement			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Salivary gland mass			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Sensitivity of teeth			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Short-bowel syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	1	4	3

Swollen tongue			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Tongue coated			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tongue discolouration			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Tongue discomfort			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Tongue disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tongue ulceration			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Tooth discolouration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tooth disorder			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	5 / 2040 (0.25%)
occurrences (all)	1	3	5
Tooth impacted			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Tooth loss			
subjects affected / exposed	3 / 2014 (0.15%)	5 / 2014 (0.25%)	4 / 2040 (0.20%)
occurrences (all)	3	5	4
Toothache			
subjects affected / exposed	15 / 2014 (0.74%)	32 / 2014 (1.59%)	25 / 2040 (1.23%)
occurrences (all)	16	39	30
Umbilical hernia			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	6 / 2040 (0.29%)
occurrences (all)	1	5	6

Upper gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Varices oesophageal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Varicose veins of abdominal wall subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Vomiting subjects affected / exposed occurrences (all)	26 / 2014 (1.29%) 34	41 / 2014 (2.04%) 52	44 / 2040 (2.16%) 53
Renal and urinary disorders			
Acute kidney injury subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	7 / 2014 (0.35%) 7	3 / 2040 (0.15%) 3
Bladder dysfunction subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Bladder pain subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Bladder prolapse subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Bladder perforation subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Calculus urinary subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	3 / 2014 (0.15%) 3	4 / 2040 (0.20%) 4
Bladder spasm subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Costovertebral angle tenderness subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
Chronic kidney disease			
subjects affected / exposed	7 / 2014 (0.35%)	28 / 2014 (1.39%)	21 / 2040 (1.03%)
occurrences (all)	7	30	22
Cystitis haemorrhagic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Cystitis noninfective			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	11 / 2014 (0.55%)	19 / 2014 (0.94%)	23 / 2040 (1.13%)
occurrences (all)	15	26	25
Haematuria			
subjects affected / exposed	5 / 2014 (0.25%)	13 / 2014 (0.65%)	12 / 2040 (0.59%)
occurrences (all)	6	14	15
Hydronephrosis			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	0	2	2
Hydroureter			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Hypertonic bladder			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Incontinence			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Kidney enlargement			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Leukocyturia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Kidney fibrosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Nephritis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Nephroangiosclerosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Nephrolithiasis			
subjects affected / exposed	8 / 2014 (0.40%)	19 / 2014 (0.94%)	5 / 2040 (0.25%)
occurrences (all)	8	19	5
Nephropathy			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	1	3	4
Nephroptosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Nephrosclerosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Nocturia			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	1	3	5
Oliguria			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Pollakiuria			
subjects affected / exposed	4 / 2014 (0.20%)	7 / 2014 (0.35%)	7 / 2040 (0.34%)
occurrences (all)	4	8	7
Polyuria			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	6 / 2040 (0.29%)
occurrences (all)	0	0	6
Proteinuria			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)

occurrences (all)	1	3	4
Pyelocaliectasis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Renal atrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Renal colic			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	0	1	5
Renal cyst			
subjects affected / exposed	11 / 2014 (0.55%)	29 / 2014 (1.44%)	34 / 2040 (1.67%)
occurrences (all)	11	30	36
Renal disorder			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Renal failure			
subjects affected / exposed	6 / 2014 (0.30%)	8 / 2014 (0.40%)	11 / 2040 (0.54%)
occurrences (all)	6	9	14
Renal impairment			
subjects affected / exposed	5 / 2014 (0.25%)	9 / 2014 (0.45%)	11 / 2040 (0.54%)
occurrences (all)	5	11	13
Renal injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Renal pain			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	0	3	3
Renal vein thrombosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Stress urinary incontinence			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Ureteric dilatation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences (all)	1	1	0
Urge incontinence subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Urinary bladder haemorrhage subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence subjects affected / exposed	13 / 2014 (0.65%)	28 / 2014 (1.39%)	21 / 2040 (1.03%)
occurrences (all)	13	28	21
Urinary retention subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	1	3	2
Urinary tract disorder subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Urinary tract inflammation subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Urine abnormality subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Urine odour abnormal subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Product issues			
Device breakage subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Device failure subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Device loosening subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			

Acne			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	2	4	0
Actinic keratosis			
subjects affected / exposed	5 / 2014 (0.25%)	9 / 2014 (0.45%)	9 / 2040 (0.44%)
occurrences (all)	5	10	14
Alopecia			
subjects affected / exposed	18 / 2014 (0.89%)	24 / 2014 (1.19%)	29 / 2040 (1.42%)
occurrences (all)	18	25	31
Alopecia areata			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Blister			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	1	5	1
Decubitus ulcer			
subjects affected / exposed	1 / 2014 (0.05%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	1	6	3
Dermal cyst			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	7 / 2040 (0.34%)
occurrences (all)	0	1	7
Dermatitis			
subjects affected / exposed	12 / 2014 (0.60%)	25 / 2014 (1.24%)	28 / 2040 (1.37%)
occurrences (all)	15	32	29
Dermatitis acneiform			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Dermatitis allergic			
subjects affected / exposed	15 / 2014 (0.74%)	28 / 2014 (1.39%)	22 / 2040 (1.08%)
occurrences (all)	15	30	33
Dermatitis atopic			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3



Dermatitis contact subjects affected / exposed occurrences (all)	8 / 2014 (0.40%) 8	10 / 2014 (0.50%) 10	7 / 2040 (0.34%) 7
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Dermatitis psoriasiform subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Diabetic foot subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Drug eruption subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	4 / 2014 (0.20%) 4	3 / 2040 (0.15%) 4
Dry skin subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	5 / 2014 (0.25%) 5	7 / 2040 (0.34%) 7
Ecchymosis subjects affected / exposed occurrences (all)	10 / 2014 (0.50%) 11	24 / 2014 (1.19%) 33	14 / 2040 (0.69%) 15
Eczema subjects affected / exposed occurrences (all)	13 / 2014 (0.65%) 14	17 / 2014 (0.84%) 22	20 / 2040 (0.98%) 28
Eczema nummular subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Erythema subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	8 / 2014 (0.40%) 9	6 / 2040 (0.29%) 7
Generalised erythema subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Haemorrhage subcutaneous subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1

Hair growth abnormal subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Hair texture abnormal subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Hand dermatitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Hyperhidrosis subjects affected / exposed occurrences (all)	8 / 2014 (0.40%) 9	10 / 2014 (0.50%) 12	6 / 2040 (0.29%) 6
Hyperkeratosis subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	6 / 2014 (0.30%) 6	5 / 2040 (0.25%) 5
Hypertrichosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Hypertrophic scar subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 2	0 / 2040 (0.00%) 0
Ingrowing nail subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	3 / 2014 (0.15%) 3	5 / 2040 (0.25%) 5
Lichen sclerosus subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Intertrigo subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	3 / 2040 (0.15%) 3
Lichen planus subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Melanosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1

Macule			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Lichenoid keratosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Nail discomfort			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Nail atrophy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Nail psoriasis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Nail ridging			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Nail disorder			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Onychoclasia			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	3	5	1
Night sweats			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	1	2	6
Neurodermatitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Onychomadesis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Onycholysis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0

Pain of skin			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Panniculitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Papule			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Pemphigus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Pemphigoid			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Prurigo			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	3	3	0
Pigmentation disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	23 / 2014 (1.14%)	43 / 2014 (2.14%)	31 / 2040 (1.52%)
occurrences (all)	24	52	34
Pruritus allergic			
subjects affected / exposed	3 / 2014 (0.15%)	5 / 2014 (0.25%)	4 / 2040 (0.20%)
occurrences (all)	3	5	5
Pruritus generalised			
subjects affected / exposed	15 / 2014 (0.74%)	20 / 2014 (0.99%)	18 / 2040 (0.88%)
occurrences (all)	17	23	18
Psoriasis			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	5 / 2040 (0.25%)
occurrences (all)	1	4	5

Rash			
subjects affected / exposed	22 / 2014 (1.09%)	39 / 2014 (1.94%)	36 / 2040 (1.76%)
occurrences (all)	25	44	41
Rash erythematous			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Rash generalised			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	1	2	4
Rash maculo-papular			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Rash macular			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	3	1
Rash papular			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	2	2	2
Rash papulosquamous			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	7 / 2014 (0.35%)	9 / 2014 (0.45%)	16 / 2040 (0.78%)
occurrences (all)	8	10	18
Rash vesicular			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Rosacea			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	0	2	5
Seborrhoea			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Seborrhoeic dermatitis			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	2	4	2

Skin atrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Skin burning sensation			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	3	0
Skin discolouration			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	3	4	4
Skin disorder			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences (all)	2	6	5
Skin exfoliation			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Skin fissures			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Skin hypopigmentation			
subjects affected / exposed	3 / 2014 (0.15%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	3	3	1
Skin induration			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Skin irritation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Skin mass			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	2	4	3
Skin lesion			
subjects affected / exposed	3 / 2014 (0.15%)	10 / 2014 (0.50%)	13 / 2040 (0.64%)
occurrences (all)	3	11	15
Skin necrosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0

Skin plaque			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	6 / 2014 (0.30%)	15 / 2014 (0.74%)	17 / 2040 (0.83%)
occurrences (all)	6	15	18
Skin ulcer haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Solar dermatitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Solar lentigo			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Stasis dermatitis			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Swelling face			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	1	3	2
Telangiectasia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Toxic skin eruption			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Umbilical discharge			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	5 / 2014 (0.25%)	6 / 2014 (0.30%)	14 / 2040 (0.69%)
occurrences (all)	5	6	14
Urticaria chronic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	2

Vascular purpura subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Xeroderma subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	193 / 2014 (9.58%) 225	380 / 2014 (18.87%) 574	343 / 2040 (16.81%) 473
Arthritis subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	12 / 2014 (0.60%) 12	12 / 2040 (0.59%) 14
Arthritis reactive subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Arthropathy subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	5 / 2014 (0.25%) 5	1 / 2040 (0.05%) 1
Autoimmune arthritis subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	1 / 2040 (0.05%) 1
Axillary mass subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	221 / 2014 (10.97%) 259	395 / 2014 (19.61%) 547	330 / 2040 (16.18%) 427
Bone cyst subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	4 / 2040 (0.20%) 4
Bone deformity subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Bone disorder			



subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Bone loss			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Bone lesion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Bone swelling			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	28 / 2014 (1.39%)	37 / 2014 (1.84%)	20 / 2040 (0.98%)
occurrences (all)	31	42	23
Cervical spinal stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Bursitis			
subjects affected / exposed	12 / 2014 (0.60%)	19 / 2014 (0.94%)	13 / 2040 (0.64%)
occurrences (all)	13	22	14
Chondrocalcinosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Coccydynia			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	2	7	3
Costochondritis			
subjects affected / exposed	5 / 2014 (0.25%)	10 / 2014 (0.50%)	5 / 2040 (0.25%)
occurrences (all)	5	11	5
Deformity thorax			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Dupuytren's contracture			

subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Enostosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Enthesopathy			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Exostosis			
subjects affected / exposed	7 / 2014 (0.35%)	16 / 2014 (0.79%)	12 / 2040 (0.59%)
occurrences (all)	9	19	12
Femoroacetabular impingement			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Fibromyalgia			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	4 / 2040 (0.20%)
occurrences (all)	3	5	4
Finger deformity			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Flank pain			
subjects affected / exposed	5 / 2014 (0.25%)	7 / 2014 (0.35%)	3 / 2040 (0.15%)
occurrences (all)	5	7	4
Foot deformity			
subjects affected / exposed	4 / 2014 (0.20%)	8 / 2014 (0.40%)	5 / 2040 (0.25%)
occurrences (all)	4	8	5
Fracture pain			
subjects affected / exposed	5 / 2014 (0.25%)	8 / 2014 (0.40%)	13 / 2040 (0.64%)
occurrences (all)	5	8	14
Gouty arthritis			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Groin pain			
subjects affected / exposed	11 / 2014 (0.55%)	18 / 2014 (0.89%)	6 / 2040 (0.29%)
occurrences (all)	11	18	6
Haemarthrosis			

subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Hand deformity			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Hypercreatinaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Interspinous osteoarthritis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Intervertebral disc degeneration			
subjects affected / exposed	2 / 2014 (0.10%)	7 / 2014 (0.35%)	7 / 2040 (0.34%)
occurrences (all)	3	8	7
Intervertebral disc disorder			
subjects affected / exposed	7 / 2014 (0.35%)	14 / 2014 (0.70%)	26 / 2040 (1.27%)
occurrences (all)	7	14	29
Intervertebral disc protrusion			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	8 / 2040 (0.39%)
occurrences (all)	2	5	11
Intervertebral disc space narrowing			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	1	3	2
Joint ankylosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Joint crepitation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Joint effusion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Joint instability			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Joint lock			

subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Joint range of motion decreased			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	2	6	3
Joint stiffness			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	4	5	2
Joint swelling			
subjects affected / exposed	7 / 2014 (0.35%)	19 / 2014 (0.94%)	27 / 2040 (1.32%)
occurrences (all)	7	20	30
Kyphosis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	1	2	3
Ligamentitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Limb deformity			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Limb discomfort			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	2	3	4
Loose body in joint			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Lordosis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Lumbar spinal stenosis			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	2 / 2040 (0.10%)
occurrences (all)	2	5	2
Metatarsalgia			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	2	3	1
Mobility decreased			

subjects affected / exposed	2 / 2014 (0.10%)	7 / 2014 (0.35%)	4 / 2040 (0.20%)
occurrences (all)	2	7	4
Muscle atrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Muscle contracture			
subjects affected / exposed	10 / 2014 (0.50%)	14 / 2014 (0.70%)	12 / 2040 (0.59%)
occurrences (all)	11	16	13
Muscle disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Muscle fatigue			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	1	3	1
Muscle spasms			
subjects affected / exposed	81 / 2014 (4.02%)	128 / 2014 (6.36%)	121 / 2040 (5.93%)
occurrences (all)	87	155	136
Muscle tightness			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	3
Muscle twitching			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Musculoskeletal chest pain			
subjects affected / exposed	22 / 2014 (1.09%)	50 / 2014 (2.48%)	30 / 2040 (1.47%)
occurrences (all)	24	56	33
Muscular weakness			
subjects affected / exposed	7 / 2014 (0.35%)	16 / 2014 (0.79%)	19 / 2040 (0.93%)
occurrences (all)	7	18	23
Musculoskeletal discomfort			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	6 / 2040 (0.29%)
occurrences (all)	2	4	6
Musculoskeletal pain			
subjects affected / exposed	83 / 2014 (4.12%)	155 / 2014 (7.70%)	145 / 2040 (7.11%)
occurrences (all)	95	188	171
Musculoskeletal stiffness			

subjects affected / exposed	5 / 2014 (0.25%)	7 / 2014 (0.35%)	9 / 2040 (0.44%)
occurrences (all)	5	7	9
Myalgia			
subjects affected / exposed	55 / 2014 (2.73%)	76 / 2014 (3.77%)	82 / 2040 (4.02%)
occurrences (all)	59	89	90
Myofascial pain syndrome			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	2 / 2040 (0.10%)
occurrences (all)	3	6	2
Myositis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Neck deformity			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Osteitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	42 / 2014 (2.09%)	75 / 2014 (3.72%)	59 / 2040 (2.89%)
occurrences (all)	46	90	66
Neck mass			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Osteolysis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	111 / 2014 (5.51%)	206 / 2014 (10.23%)	189 / 2040 (9.26%)
occurrences (all)	131	279	243
Osteochondrosis			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	5 / 2040 (0.25%)
occurrences (all)	1	3	5
Osteoporosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	0	1	4

Osteonecrosis of jaw subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Osteosclerosis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Pain in extremity subjects affected / exposed occurrences (all)	129 / 2014 (6.41%) 150	253 / 2014 (12.56%) 350	230 / 2040 (11.27%) 308
Pain in jaw subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 5	4 / 2014 (0.20%) 5	4 / 2040 (0.20%) 4
Periarthritis subjects affected / exposed occurrences (all)	6 / 2014 (0.30%) 6	16 / 2014 (0.79%) 17	9 / 2040 (0.44%) 10
Polyarthritits subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Plantar fasciitis subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 3	8 / 2014 (0.40%) 9	8 / 2040 (0.39%) 9
Periostitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Polymyalgia rheumatica subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	5 / 2014 (0.25%) 5	3 / 2040 (0.15%) 5
Rheumatoid arthritis subjects affected / exposed occurrences (all)	6 / 2014 (0.30%) 8	10 / 2014 (0.50%) 20	9 / 2040 (0.44%) 12
Sacroiliitis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Rotator cuff syndrome subjects affected / exposed occurrences (all)	7 / 2014 (0.35%) 7	12 / 2014 (0.60%) 12	10 / 2040 (0.49%) 12

Scoliosis			
subjects affected / exposed	4 / 2014 (0.20%)	13 / 2014 (0.65%)	12 / 2040 (0.59%)
occurrences (all)	4	14	12
Seronegative arthritis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Sjogren's syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Soft tissue disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Spinal column stenosis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3
Soft tissue mass			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Spinal osteoarthritis			
subjects affected / exposed	26 / 2014 (1.29%)	52 / 2014 (2.58%)	50 / 2040 (2.45%)
occurrences (all)	29	58	52
Spinal disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Spinal deformity			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	1	2	3
Spondylitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	4
Spondyloarthropathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Spinal pain			
subjects affected / exposed	14 / 2014 (0.70%)	44 / 2014 (2.18%)	58 / 2040 (2.84%)
occurrences (all)	16	52	67



Spondylolisthesis			
subjects affected / exposed	5 / 2014 (0.25%)	12 / 2014 (0.60%)	9 / 2040 (0.44%)
occurrences (all)	6	13	9
Spondylolysis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Sympathetic posterior cervical syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Synovial cyst			
subjects affected / exposed	4 / 2014 (0.20%)	8 / 2014 (0.40%)	9 / 2040 (0.44%)
occurrences (all)	4	8	9
Synovitis			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	0 / 2040 (0.00%)
occurrences (all)	2	4	0
Temporomandibular joint syndrome			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	2	3	3
Systemic lupus erythematosus			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tendon disorder			
subjects affected / exposed	4 / 2014 (0.20%)	5 / 2014 (0.25%)	4 / 2040 (0.20%)
occurrences (all)	4	5	6
Tendon pain			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Tendonitis			
subjects affected / exposed	17 / 2014 (0.84%)	34 / 2014 (1.69%)	20 / 2040 (0.98%)
occurrences (all)	17	36	24
Tenosynovitis stenosans			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Tenosynovitis			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)

occurrences (all)	1	3	1
Trismus			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Torticollis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Trigger finger			
subjects affected / exposed	10 / 2014 (0.50%)	15 / 2014 (0.74%)	13 / 2040 (0.64%)
occurrences (all)	10	16	14
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	0	1	3
Vertebral wedging			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Adrenal insufficiency			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Adrenal mass			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Empty sella syndrome			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Autoimmune thyroiditis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	1	2	5
Goitre			
subjects affected / exposed	10 / 2014 (0.50%)	22 / 2014 (1.09%)	21 / 2040 (1.03%)
occurrences (all)	10	22	21
Hypercorticism			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hyperparathyroidism			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Hyperparathyroidism primary			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Hyperparathyroidism secondary			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	20 / 2040 (0.98%)
occurrences (all)	5	10	23
Hypothyroidism			
subjects affected / exposed	13 / 2014 (0.65%)	35 / 2014 (1.74%)	45 / 2040 (2.21%)
occurrences (all)	13	37	46
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Thyroid cyst			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Thyroid disorder			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Thyroid mass			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences (all)	2	6	4
Thyroiditis chronic			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Toxic goitre			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Toxic nodular goitre subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Metabolism and nutrition disorders			
Abnormal loss of weight subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	4 / 2040 (0.20%) 4
Acquired mixed hyperlipidaemia subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	0 / 2040 (0.00%) 0
Carbohydrate intolerance subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	6 / 2014 (0.30%) 6	4 / 2040 (0.20%) 4
Calcium metabolism disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	3 / 2040 (0.15%) 3
Decreased appetite subjects affected / exposed occurrences (all)	19 / 2014 (0.94%) 19	29 / 2014 (1.44%) 29	35 / 2040 (1.72%) 40
Dehydration subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	5 / 2014 (0.25%) 5	10 / 2040 (0.49%) 10
Diabetes mellitus subjects affected / exposed occurrences (all)	12 / 2014 (0.60%) 14	27 / 2014 (1.34%) 29	28 / 2040 (1.37%) 30
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	5 / 2014 (0.25%) 5	7 / 2040 (0.34%) 7
Dyslipidaemia subjects affected / exposed occurrences (all)	28 / 2014 (1.39%) 28	64 / 2014 (3.18%) 64	55 / 2040 (2.70%) 56
Fluid overload subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Electrolyte imbalance subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)

occurrences (all)	1	3	4
Fluid retention			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Folate deficiency			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Food intolerance			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Glucose tolerance impaired			
subjects affected / exposed	8 / 2014 (0.40%)	11 / 2014 (0.55%)	6 / 2040 (0.29%)
occurrences (all)	8	11	6
Gluten sensitivity			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Gout			
subjects affected / exposed	3 / 2014 (0.15%)	7 / 2014 (0.35%)	4 / 2040 (0.20%)
occurrences (all)	3	8	4
Hyperammonaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	3	7	3
Hypercholesterolaemia			
subjects affected / exposed	16 / 2014 (0.79%)	36 / 2014 (1.79%)	46 / 2040 (2.25%)
occurrences (all)	16	37	46
Hyperhomocysteinaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	13 / 2014 (0.65%)	20 / 2014 (0.99%)	17 / 2040 (0.83%)
occurrences (all)	13	22	17
Hyperlipidaemia			
subjects affected / exposed	6 / 2014 (0.30%)	17 / 2014 (0.84%)	18 / 2040 (0.88%)

occurrences (all)	6	17	19
Hyperkalaemia			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	9 / 2040 (0.44%)
occurrences (all)	2	7	11
Hypermagnesaemia			
subjects affected / exposed	4 / 2014 (0.20%)	7 / 2014 (0.35%)	2 / 2040 (0.10%)
occurrences (all)	7	10	2
Hypernatraemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hyperphagia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Hypertriglyceridaemia			
subjects affected / exposed	3 / 2014 (0.15%)	9 / 2014 (0.45%)	5 / 2040 (0.25%)
occurrences (all)	3	9	5
Hyperuricaemia			
subjects affected / exposed	4 / 2014 (0.20%)	12 / 2014 (0.60%)	18 / 2040 (0.88%)
occurrences (all)	4	12	20
Hyperphosphataemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	3	3
Hypervitaminosis D			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Hypochloraemia			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences (all)	1	2	4
Hypocalcaemia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	1	1	4
Hypoglycaemia			
subjects affected / exposed	6 / 2014 (0.30%)	14 / 2014 (0.70%)	12 / 2040 (0.59%)

occurrences (all)	7	16	13
Hypomagnesaemia			
subjects affected / exposed	0 / 2014 (0.00%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	0	4	2
Hypokalaemia			
subjects affected / exposed	8 / 2014 (0.40%)	20 / 2014 (0.99%)	27 / 2040 (1.32%)
occurrences (all)	8	21	29
Hypophosphataemia			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	7 / 2014 (0.35%)	26 / 2014 (1.29%)	23 / 2040 (1.13%)
occurrences (all)	7	26	27
Hypoproteinaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hypovitaminosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Hypovolaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Impaired fasting glucose			
subjects affected / exposed	5 / 2014 (0.25%)	8 / 2014 (0.40%)	6 / 2040 (0.29%)
occurrences (all)	5	8	6
Increased appetite			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	1	4	3
Lipid metabolism disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Metabolic acidosis			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)

occurrences (all)	0	2	0
Malnutrition			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	3
Metabolic disorder			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Mineral deficiency			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Obesity			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences (all)	3	6	4
Polydipsia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	9 / 2014 (0.45%)	13 / 2014 (0.65%)	16 / 2040 (0.78%)
occurrences (all)	9	13	16
Underweight			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vitamin B complex deficiency			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Vitamin B12 deficiency			
subjects affected / exposed	0 / 2014 (0.00%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences (all)	0	6	5
Vitamin D deficiency			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	0	3	4
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Abscess limb			



subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	0	2	3
Abscess oral			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Acute sinusitis			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	6 / 2040 (0.29%)
occurrences (all)	2	6	6
Amoebic dysentery			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Angular cheilitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Appendiceal abscess			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Appendicitis			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Arthritis bacterial			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Arthritis infective			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Asymptomatic bacteriuria			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences (all)	3	7	5
Atypical pneumonia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Bacterial diarrhoea			

subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	2	3	1
Bacterial infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Bacterial tracheitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Bacterial vaginosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Bacterial vulvovaginitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Bacteriuria			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Bartholin's abscess			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Body tinea			
subjects affected / exposed	3 / 2014 (0.15%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	3	3	1
Borrelia infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Breast abscess			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Bronchiolitis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Bronchitis			
subjects affected / exposed	100 / 2014 (4.97%)	187 / 2014 (9.29%)	176 / 2040 (8.63%)
occurrences (all)	110	242	236
Bronchitis bacterial			

subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	7 / 2014 (0.35%) 7	9 / 2040 (0.44%) 12
Bronchitis viral subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	1 / 2040 (0.05%) 1
Candida infection subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Carbuncle subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Cellulitis subjects affected / exposed occurrences (all)	11 / 2014 (0.55%) 12	24 / 2014 (1.19%) 27	21 / 2040 (1.03%) 26
Cellulitis staphylococcal subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Cervicitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	3 / 2040 (0.15%) 3
Chikungunya virus infection subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	7 / 2014 (0.35%) 7	4 / 2040 (0.20%) 4
Chronic sinusitis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	3 / 2040 (0.15%) 3
Chronic tonsillitis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Clostridium difficile colitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Conjunctivitis			

subjects affected / exposed	16 / 2014 (0.79%)	36 / 2014 (1.79%)	31 / 2040 (1.52%)
occurrences (all)	16	37	33
Conjunctivitis bacterial			
subjects affected / exposed	10 / 2014 (0.50%)	14 / 2014 (0.70%)	11 / 2040 (0.54%)
occurrences (all)	10	14	13
Conjunctivitis viral			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Corneal infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed	27 / 2014 (1.34%)	49 / 2014 (2.43%)	39 / 2040 (1.91%)
occurrences (all)	35	64	57
Cystitis bacterial			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	1	3	2
Dacryocanaliculitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Dacryocystitis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Dengue fever			
subjects affected / exposed	2 / 2014 (0.10%)	10 / 2014 (0.50%)	5 / 2040 (0.25%)
occurrences (all)	2	11	5
Dermatitis infected			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	2
Dermo-hypodermatitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Diarrhoea infectious			

subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	2
Diverticulitis			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	7 / 2040 (0.34%)
occurrences (all)	3	6	7
Ear infection			
subjects affected / exposed	5 / 2014 (0.25%)	12 / 2014 (0.60%)	5 / 2040 (0.25%)
occurrences (all)	5	12	5
Ear infection bacterial			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3
Ear infection fungal			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	5
Ear infection viral			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Enterobiasis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Enterococcal infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Enterocolitis viral			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Erysipelas			
subjects affected / exposed	3 / 2014 (0.15%)	13 / 2014 (0.65%)	7 / 2040 (0.34%)
occurrences (all)	3	14	9
Escherichia urinary tract infection			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	1	3	3
Eye infection			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	0	3	2
Eye infection bacterial			

subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	0	2	2
Eyelid infection			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Flavivirus infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Febrile infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Fungal infection			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	3	5	2
Fungal skin infection			
subjects affected / exposed	6 / 2014 (0.30%)	7 / 2014 (0.35%)	14 / 2040 (0.69%)
occurrences (all)	6	7	15
Folliculitis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Furuncle			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	8 / 2040 (0.39%)
occurrences (all)	3	6	8
Gastritis bacterial			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	41 / 2014 (2.04%)	73 / 2014 (3.62%)	64 / 2040 (3.14%)
occurrences (all)	42	82	73
Gastroenteritis rotavirus			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Gastroenteritis bacterial			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Gastroenteritis viral			

subjects affected / exposed	15 / 2014 (0.74%)	25 / 2014 (1.24%)	27 / 2040 (1.32%)
occurrences (all)	16	27	29
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal fungal infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	1	4	1
Gastrointestinal viral infection			
subjects affected / exposed	1 / 2014 (0.05%)	9 / 2014 (0.45%)	5 / 2040 (0.25%)
occurrences (all)	1	9	5
Genital candidiasis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Genital herpes			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	2	2	3
Genital herpes zoster			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Genital infection fungal			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Genitourinary tract infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Gingival abscess			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	3 / 2040 (0.15%)
occurrences (all)	1	4	3
Giardiasis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Gingivitis			

subjects affected / exposed	11 / 2014 (0.55%)	18 / 2014 (0.89%)	16 / 2040 (0.78%)
occurrences (all)	12	21	23
Groin infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
H1N1 influenza			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Helicobacter gastritis			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	3 / 2040 (0.15%)
occurrences (all)	2	5	3
Helicobacter infection			
subjects affected / exposed	5 / 2014 (0.25%)	13 / 2014 (0.65%)	10 / 2040 (0.49%)
occurrences (all)	5	13	11
Helminthic infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Hepatitis B			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Hepatic echinococcosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hepatitis C			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Herpes dermatitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Herpes ophthalmic			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Herpes simplex			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	1	1	5
Herpes virus infection			



subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 3	1 / 2014 (0.05%) 4	1 / 2040 (0.05%) 1
Herpes zoster subjects affected / exposed occurrences (all)	21 / 2014 (1.04%) 21	45 / 2014 (2.23%) 46	45 / 2040 (2.21%) 48
Herpes zoster disseminated subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Herpes zoster infection neurological subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Herpes zoster oticus subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Hordeolum subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Impetigo subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Implant site infection subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Incision site infection subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Infected bite subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	4 / 2014 (0.20%) 4	2 / 2040 (0.10%) 2
Infected fistula subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Infected skin ulcer subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	4 / 2014 (0.20%) 4	4 / 2040 (0.20%) 4
Infection			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Infection parasitic			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	2	5	2
Influenza			
subjects affected / exposed	57 / 2014 (2.83%)	119 / 2014 (5.91%)	105 / 2040 (5.15%)
occurrences (all)	68	155	128
Injection site infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Kidney infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Joint abscess			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Labyrinthitis			
subjects affected / exposed	8 / 2014 (0.40%)	12 / 2014 (0.60%)	10 / 2040 (0.49%)
occurrences (all)	8	13	10
Laryngitis			
subjects affected / exposed	4 / 2014 (0.20%)	15 / 2014 (0.74%)	16 / 2040 (0.78%)
occurrences (all)	4	16	18
Laryngitis bacterial			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Laryngitis viral			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Latent syphilis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Lip infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Liver abscess			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Localised infection			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	7 / 2040 (0.34%)
occurrences (all)	1	3	7
Lower respiratory tract infection			
subjects affected / exposed	9 / 2014 (0.45%)	17 / 2014 (0.84%)	24 / 2040 (1.18%)
occurrences (all)	13	31	44
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Lyme disease			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Lymphadenitis bacterial			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Lymphangitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Molluscum contagiosum			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Mycobacterium abscessus infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Nail bed infection bacterial			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	43 / 2014 (2.14%)	70 / 2014 (3.48%)	72 / 2040 (3.53%)
occurrences (all)	50	87	88

Nail infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Oesophageal candidiasis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Onychomycosis			
subjects affected / exposed	7 / 2014 (0.35%)	18 / 2014 (0.89%)	18 / 2040 (0.88%)
occurrences (all)	7	18	19
Oophoritis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Oral candidiasis			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	8 / 2040 (0.39%)
occurrences (all)	4	7	9
Oral bacterial infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Oral fungal infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	4 / 2040 (0.20%)
occurrences (all)	0	0	6
Oral herpes			
subjects affected / exposed	7 / 2014 (0.35%)	11 / 2014 (0.55%)	15 / 2040 (0.74%)
occurrences (all)	8	15	18
Oral infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Oral viral infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Osteomyelitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	5 / 2014 (0.25%)	7 / 2014 (0.35%)	6 / 2040 (0.29%)
occurrences (all)	7	10	6
Otitis externa bacterial			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Otitis media			
subjects affected / exposed	4 / 2014 (0.20%)	6 / 2014 (0.30%)	5 / 2040 (0.25%)
occurrences (all)	4	6	6
Otitis media acute			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	2	2	2
Otitis media chronic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Otitis media bacterial			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Parasitic gastroenteritis			
subjects affected / exposed	3 / 2014 (0.15%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)
occurrences (all)	4	4	3
Paronychia			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	5 / 2040 (0.25%)
occurrences (all)	1	4	5
Parotitis			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Periodontitis			
subjects affected / exposed	6 / 2014 (0.30%)	9 / 2014 (0.45%)	14 / 2040 (0.69%)
occurrences (all)	6	10	15
Peritonitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Peritonsillar abscess			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Pharyngitis			
subjects affected / exposed	36 / 2014 (1.79%)	50 / 2014 (2.48%)	57 / 2040 (2.79%)
occurrences (all)	39	63	63
Pharyngitis bacterial			
subjects affected / exposed	3 / 2014 (0.15%)	5 / 2014 (0.25%)	11 / 2040 (0.54%)
occurrences (all)	3	5	12
Pharyngotonsillitis			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	2	4	5
Pneumonia			
subjects affected / exposed	21 / 2014 (1.04%)	53 / 2014 (2.63%)	46 / 2040 (2.25%)
occurrences (all)	23	58	60
Pneumococcal infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Pneumonia adenoviral			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pneumonia bacterial			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	3 / 2040 (0.15%)
occurrences (all)	4	10	3
Pneumonia escherichia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Pneumonia viral			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Post procedural infection			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1

Postoperative wound infection subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	0 / 2040 (0.00%) 0
Pulpitis dental subjects affected / exposed occurrences (all)	6 / 2014 (0.30%) 7	10 / 2014 (0.50%) 11	7 / 2040 (0.34%) 9
Pyelitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Pyelocystitis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Pyelonephritis subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 3	3 / 2014 (0.15%) 5	2 / 2040 (0.10%) 2
Pyelonephritis chronic subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	2 / 2014 (0.10%) 2	3 / 2040 (0.15%) 3
Pyometra subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Rash pustular subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Respiratory tract infection subjects affected / exposed occurrences (all)	16 / 2014 (0.79%) 17	39 / 2014 (1.94%) 45	47 / 2040 (2.30%) 57
Respiratory tract infection viral subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	6 / 2014 (0.30%) 6	10 / 2040 (0.49%) 13
Respiratory tract infection bacterial subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 3	0 / 2040 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	13 / 2014 (0.65%) 14	20 / 2014 (0.99%) 22	19 / 2040 (0.93%) 22

Root canal infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Septic encephalopathy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Septic shock			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Sialoadenitis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Sinobronchitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	28 / 2014 (1.39%)	50 / 2014 (2.48%)	29 / 2040 (1.42%)
occurrences (all)	30	61	29
Sinusitis bacterial			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	2	3	2
Skin bacterial infection			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Skin candida			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Soft tissue infection			
subjects affected / exposed	4 / 2014 (0.20%)	7 / 2014 (0.35%)	2 / 2040 (0.10%)
occurrences (all)	4	7	2
Skin infection			
subjects affected / exposed	1 / 2014 (0.05%)	7 / 2014 (0.35%)	4 / 2040 (0.20%)
occurrences (all)	1	7	4



Staphylococcal infection subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Subcutaneous abscess subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	4 / 2014 (0.20%) 4	2 / 2040 (0.10%) 2
Tick-borne fever subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Tinea capitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Tinea infection subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Tinea pedis subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	4 / 2014 (0.20%) 5	6 / 2040 (0.29%) 6
Tonsillitis subjects affected / exposed occurrences (all)	7 / 2014 (0.35%) 7	13 / 2014 (0.65%) 13	18 / 2040 (0.88%) 19
Tonsillitis bacterial subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	3 / 2014 (0.15%) 3	0 / 2040 (0.00%) 0
Tooth abscess subjects affected / exposed occurrences (all)	6 / 2014 (0.30%) 6	16 / 2014 (0.79%) 18	13 / 2040 (0.64%) 15
Tooth infection subjects affected / exposed occurrences (all)	9 / 2014 (0.45%) 9	14 / 2014 (0.70%) 14	12 / 2040 (0.59%) 12
Tracheitis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	2 / 2040 (0.10%) 2
Tracheobronchitis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	5 / 2040 (0.25%) 6

Tuberculosis subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Upper respiratory fungal infection subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	132 / 2014 (6.55%) 212	226 / 2014 (11.22%) 481	205 / 2040 (10.05%) 444
Upper respiratory tract infection bacterial subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	4 / 2040 (0.20%) 4
Urethritis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Urinary tract infection bacterial subjects affected / exposed occurrences (all)	13 / 2014 (0.65%) 15	17 / 2014 (0.84%) 20	13 / 2040 (0.64%) 15
Urinary tract infection subjects affected / exposed occurrences (all)	128 / 2014 (6.36%) 151	244 / 2014 (12.12%) 358	180 / 2040 (8.82%) 231
Urinary tract infection enterococcal subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Urinary tract infection fungal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Urinary tract infection pseudomonal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 2
Urinary tract infection staphylococcal subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Vaginal abscess subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences (all)	0	1	0
Vaginal infection			
subjects affected / exposed	3 / 2014 (0.15%)	7 / 2014 (0.35%)	5 / 2040 (0.25%)
occurrences (all)	3	7	5
Varicella zoster virus infection			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	3	4	0
Viral diarrhoea			
subjects affected / exposed	5 / 2014 (0.25%)	10 / 2014 (0.50%)	4 / 2040 (0.20%)
occurrences (all)	5	10	5
Viral infection			
subjects affected / exposed	7 / 2014 (0.35%)	14 / 2014 (0.70%)	10 / 2040 (0.49%)
occurrences (all)	8	17	12
Viral rash			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Viral pharyngitis			
subjects affected / exposed	3 / 2014 (0.15%)	5 / 2014 (0.25%)	5 / 2040 (0.25%)
occurrences (all)	3	5	5
Viral rhinitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	0	1	3
Viral skin infection			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	233 / 2014 (11.57%)	406 / 2014 (20.16%)	388 / 2040 (19.02%)
occurrences (all)	283	697	621
Vulval abscess			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vulvitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal candidiasis			

subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	2 / 2040 (0.10%) 2
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 4	4 / 2014 (0.20%) 5	5 / 2040 (0.25%) 5
Vulvovaginitis subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	2 / 2014 (0.10%) 2	2 / 2040 (0.10%) 2
Wound infection subjects affected / exposed occurrences (all)	6 / 2014 (0.30%) 7	11 / 2014 (0.55%) 14	3 / 2040 (0.15%) 3
Wound infection bacterial subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	4 / 2014 (0.20%) 4	3 / 2040 (0.15%) 3
Wound infection staphylococcal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Vascular disorders			
Aneurysm subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Angiosclerosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Aortic aneurysm subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	3 / 2040 (0.15%) 3
Aortic arteriosclerosis subjects affected / exposed occurrences (all)	9 / 2014 (0.45%) 9	15 / 2014 (0.74%) 16	27 / 2040 (1.32%) 28
Aortic dilatation subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	3 / 2014 (0.15%) 3	3 / 2040 (0.15%) 3
Aortic calcification subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	2 / 2040 (0.10%) 2

Aortic elongation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Aortic disorder			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Aortic stenosis			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences (all)	2	6	4
Aortic thrombosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Arterial insufficiency			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Arteriosclerosis			
subjects affected / exposed	8 / 2014 (0.40%)	21 / 2014 (1.04%)	17 / 2040 (0.83%)
occurrences (all)	8	22	17
Arterial stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Arterial occlusive disease			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Blood pressure fluctuation			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	7 / 2040 (0.34%)
occurrences (all)	1	2	7
Blood pressure inadequately controlled			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Circulatory collapse			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Deep vein thrombosis			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	3	7	3

Haematoma subjects affected / exposed occurrences (all)	19 / 2014 (0.94%) 21	43 / 2014 (2.14%) 51	30 / 2040 (1.47%) 35
Essential hypertension subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	3 / 2014 (0.15%) 3	3 / 2040 (0.15%) 3
Diastolic hypotension subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	130 / 2014 (6.45%) 139	232 / 2014 (11.52%) 270	233 / 2040 (11.42%) 275
Hot flush subjects affected / exposed occurrences (all)	5 / 2014 (0.25%) 5	5 / 2014 (0.25%) 5	5 / 2040 (0.25%) 6
Hypertensive angiopathy subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Hypertensive crisis subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	6 / 2014 (0.30%) 6	12 / 2040 (0.59%) 12
Hypertensive emergency subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Ischaemia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Hypotension subjects affected / exposed occurrences (all)	10 / 2014 (0.50%) 11	15 / 2014 (0.74%) 17	10 / 2040 (0.49%) 10
Intermittent claudication subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	4 / 2014 (0.20%) 5	2 / 2040 (0.10%) 2
Labile hypertension subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences (all)	1	1	0
Labile blood pressure			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Lymphostasis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Microangiopathy			
subjects affected / exposed	0 / 2014 (0.00%)	5 / 2014 (0.25%)	1 / 2040 (0.05%)
occurrences (all)	0	5	1
Lymphoedema			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	5 / 2040 (0.25%)
occurrences (all)	1	3	6
Orthostatic hypotension			
subjects affected / exposed	1 / 2014 (0.05%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	1	4	5
Pallor			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Pelvic venous thrombosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Peripheral arterial occlusive disease			
subjects affected / exposed	2 / 2014 (0.10%)	7 / 2014 (0.35%)	9 / 2040 (0.44%)
occurrences (all)	2	7	9
Peripheral artery aneurysm			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Peripheral artery stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	5
Peripheral artery thrombosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Peripheral coldness			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)

occurrences (all)	0	1	1
Peripheral ischaemia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Peripheral vascular disorder			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	9 / 2040 (0.44%)
occurrences (all)	1	3	10
Peripheral venous disease			
subjects affected / exposed	5 / 2014 (0.25%)	17 / 2014 (0.84%)	19 / 2040 (0.93%)
occurrences (all)	5	19	19
Phlebitis			
subjects affected / exposed	4 / 2014 (0.20%)	8 / 2014 (0.40%)	6 / 2040 (0.29%)
occurrences (all)	4	8	8
Phlebitis deep			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Phlebitis superficial			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	2	3	5
Poor peripheral circulation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	2	3	4
Post thrombotic syndrome			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Raynaud's phenomenon			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Subgaleal haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Thrombophlebitis			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	2	6	3
Thrombophlebitis superficial			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)



occurrences (all)	1	2	4
Thrombosis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Varicophlebitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Varicose ulceration			
subjects affected / exposed	4 / 2014 (0.20%)	10 / 2014 (0.50%)	7 / 2040 (0.34%)
occurrences (all)	4	12	8
Varicose vein			
subjects affected / exposed	14 / 2014 (0.70%)	34 / 2014 (1.69%)	24 / 2040 (1.18%)
occurrences (all)	15	38	24
Varicose vein ruptured			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vascular calcification			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)
occurrences (all)	0	0	3
Vascular insufficiency			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Vasculitis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vasodilatation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vena cava thrombosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Venous thrombosis			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	2	2	1
Venous thrombosis limb			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)

occurrences (all)	1	3	2
Surgical and medical procedures			
Blepharoplasty			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Dental care			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Female genital operation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Intervertebral disc operation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Nerve block			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Oral surgery			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Skin neoplasm excision			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Spinal fusion surgery			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Tooth extraction			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	0	2	1
Suture insertion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Adenocarcinoma of colon subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Adrenal neoplasm subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Adrenal adenoma subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	2 / 2040 (0.10%) 2
Adenoma benign subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Basal cell carcinoma subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	17 / 2014 (0.84%) 20	13 / 2040 (0.64%) 16
Angiomyolipoma subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Benign lung neoplasm subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	4 / 2014 (0.20%) 4	2 / 2040 (0.10%) 2
Benign female reproductive tract neoplasm subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Benign breast neoplasm subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	4 / 2014 (0.20%) 4	3 / 2040 (0.15%) 3
Benign neoplasm of eyelid subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Benign neoplasm subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	1 / 2040 (0.05%) 1
Benign neoplasm of adrenal gland subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1

Benign neoplasm of skin subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	5 / 2040 (0.25%) 5
Benign neoplasm of thyroid gland subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	5 / 2014 (0.25%) 5	8 / 2040 (0.39%) 8
Bowen's disease subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Breast cancer subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Benign renal neoplasm subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Breast fibroma subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Chronic myeloid leukaemia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Chronic lymphocytic leukaemia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Colon neoplasm subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Colon adenoma subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Essential thrombocythaemia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Eye naevus subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1

Fibroadenoma of breast subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Fibrous histiocytoma subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Fibroma subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Gastrointestinal tract adenoma subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Haemangioma subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Haemangioma of bone subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Haemangioma of liver subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	4 / 2040 (0.20%) 5
Hepatic neoplasm subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Hypergammaglobulinaemia benign monoclonal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Invasive breast carcinoma subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Infected neoplasm subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Lipoma subjects affected / exposed	1 / 2014 (0.05%)	7 / 2014 (0.35%)	2 / 2040 (0.10%)

occurrences (all)	1	7	2
Lung neoplasm			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Lung neoplasm malignant			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Malignant melanoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	3
Lymphoma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Melanocytic naevus			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	2	3	4
Malignant neoplasm of eyelid			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Meningioma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Monoclonal gammopathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	2
Myelodysplastic syndrome			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Neoplasm malignant			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Non-Hodgkin's lymphoma			
unspecified histology indolent stage I			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Oesophageal adenocarcinoma stage 0			

subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Osteoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Osteochondroma			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Primary myelofibrosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Pyogenic granuloma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Rectal adenoma			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Renal neoplasm			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	1	3	0
Retroperitoneal cancer			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Seborrhoeic keratosis			
subjects affected / exposed	2 / 2014 (0.10%)	6 / 2014 (0.30%)	4 / 2040 (0.20%)
occurrences (all)	2	6	5
Skin papilloma			
subjects affected / exposed	5 / 2014 (0.25%)	9 / 2014 (0.45%)	4 / 2040 (0.20%)
occurrences (all)	5	9	4
Squamous cell carcinoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	0	1	4
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Sweat gland tumour			

subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Thyroid cancer subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Uterine leiomyoma subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	4 / 2014 (0.20%) 4	0 / 2040 (0.00%) 0
Vulval cancer subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Immune system disorders			
Allergy to animal subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Allergy to arthropod bite subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	4 / 2040 (0.20%) 4
Allergy to chemicals subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	3 / 2040 (0.15%) 3
Drug hypersensitivity subjects affected / exposed occurrences (all)	7 / 2014 (0.35%) 7	12 / 2014 (0.60%) 12	7 / 2040 (0.34%) 7
Food allergy subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	0 / 2040 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	7 / 2014 (0.35%) 7	4 / 2040 (0.20%) 6
Iodine allergy subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0



Mite allergy subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Oral allergy syndrome subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Seasonal allergy subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	6 / 2014 (0.30%) 6	10 / 2040 (0.49%) 11
Social circumstances			
Diet noncompliance subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Immobile subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
General disorders and administration site conditions			
Administration site erythema subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 2
Administration site haematoma subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Administration site pain subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 2	1 / 2014 (0.05%) 2	2 / 2040 (0.10%) 2
Administration site pruritus subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Administration site reaction subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Administration site swelling subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Adverse drug reaction			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Asthenia			
subjects affected / exposed	52 / 2014 (2.58%)	84 / 2014 (4.17%)	74 / 2040 (3.63%)
occurrences (all)	57	101	85
Axillary pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Calcinosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Catheter site extravasation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Chest discomfort			
subjects affected / exposed	2 / 2014 (0.10%)	8 / 2014 (0.40%)	6 / 2040 (0.29%)
occurrences (all)	2	8	6
Chest pain			
subjects affected / exposed	12 / 2014 (0.60%)	28 / 2014 (1.39%)	21 / 2040 (1.03%)
occurrences (all)	14	32	22
Chills			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	9 / 2040 (0.44%)
occurrences (all)	1	1	10
Complication associated with device			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cyst			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Drug intolerance			
subjects affected / exposed	8 / 2014 (0.40%)	14 / 2014 (0.70%)	3 / 2040 (0.15%)
occurrences (all)	8	14	5
Discomfort			
subjects affected / exposed	1 / 2014 (0.05%)	5 / 2014 (0.25%)	5 / 2040 (0.25%)
occurrences (all)	1	5	7
Exercise tolerance decreased			

subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Exercise tolerance increased			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Extravasation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Eye complication associated with device			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Face oedema			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	2
Facial pain			
subjects affected / exposed	2 / 2014 (0.10%)	5 / 2014 (0.25%)	4 / 2040 (0.20%)
occurrences (all)	2	5	4
Fatigue			
subjects affected / exposed	23 / 2014 (1.14%)	38 / 2014 (1.89%)	30 / 2040 (1.47%)
occurrences (all)	23	41	30
Feeling abnormal			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Feeling hot			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	0 / 2040 (0.00%)
occurrences (all)	2	3	0
Foreign body reaction			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
General physical health deterioration			
subjects affected / exposed	0 / 2014 (0.00%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	0	4	1
Gait disturbance			
subjects affected / exposed	3 / 2014 (0.15%)	10 / 2014 (0.50%)	3 / 2040 (0.15%)
occurrences (all)	3	10	3

Generalised oedema subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	3 / 2014 (0.15%) 3	0 / 2040 (0.00%) 0
Hernia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Impaired healing subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	3 / 2014 (0.15%) 3	2 / 2040 (0.10%) 3
Impaired self-care subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Influenza like illness subjects affected / exposed occurrences (all)	26 / 2014 (1.29%) 26	32 / 2014 (1.59%) 36	17 / 2040 (0.83%) 17
Injection site bruising subjects affected / exposed occurrences (all)	7 / 2014 (0.35%) 8	7 / 2014 (0.35%) 8	3 / 2040 (0.15%) 3
Injection site erythema subjects affected / exposed occurrences (all)	9 / 2014 (0.45%) 9	9 / 2014 (0.45%) 9	26 / 2040 (1.27%) 53
Injection site haematoma subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	2 / 2014 (0.10%) 2	3 / 2040 (0.15%) 4
Injection site haemorrhage subjects affected / exposed occurrences (all)	7 / 2014 (0.35%) 7	7 / 2014 (0.35%) 7	10 / 2040 (0.49%) 13
Injection site hypersensitivity subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Injection site inflammation subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Injection site macule subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1

Injection site oedema subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Injection site pain subjects affected / exposed occurrences (all)	24 / 2014 (1.19%) 36	24 / 2014 (1.19%) 36	32 / 2040 (1.57%) 70
Injection site papule subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Injection site pruritus subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	4 / 2014 (0.20%) 4	17 / 2040 (0.83%) 26
Injection site rash subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	2 / 2014 (0.10%) 2	8 / 2040 (0.39%) 12
Injection site swelling subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	7 / 2040 (0.34%) 11
Injection site urticaria subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	3 / 2040 (0.15%) 5
Injection site vesicles subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Injection site warmth subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	2 / 2040 (0.10%) 2
Injury associated with device subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Local swelling subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	2 / 2014 (0.10%) 2	1 / 2040 (0.05%) 1
Localised oedema subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0

Malaise			
subjects affected / exposed	14 / 2014 (0.70%)	23 / 2014 (1.14%)	21 / 2040 (1.03%)
occurrences (all)	16	26	22
Mass			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Medical device pain			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Medical device site joint pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Mucosal atrophy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Mucosal hyperaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Nodule			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	2 / 2040 (0.10%)
occurrences (all)	4	9	2
Non-cardiac chest pain			
subjects affected / exposed	25 / 2014 (1.24%)	39 / 2014 (1.94%)	30 / 2040 (1.47%)
occurrences (all)	29	48	31
Oedema			
subjects affected / exposed	3 / 2014 (0.15%)	6 / 2014 (0.30%)	2 / 2040 (0.10%)
occurrences (all)	3	6	3
Oedema peripheral			
subjects affected / exposed	37 / 2014 (1.84%)	81 / 2014 (4.02%)	64 / 2040 (3.14%)
occurrences (all)	42	99	70
Pain			
subjects affected / exposed	10 / 2014 (0.50%)	21 / 2014 (1.04%)	19 / 2040 (0.93%)
occurrences (all)	13	26	19

Peripheral swelling subjects affected / exposed occurrences (all)	13 / 2014 (0.65%) 14	35 / 2014 (1.74%) 41	36 / 2040 (1.76%) 47
Polyp subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Pseudocyst subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Pyrexia subjects affected / exposed occurrences (all)	18 / 2014 (0.89%) 19	33 / 2014 (1.64%) 36	28 / 2040 (1.37%) 39
Sensation of foreign body subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Suprapubic pain subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 2	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Swelling subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Ulcer subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Ulcer haemorrhage subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Vaccination site rash subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Vessel puncture site erythema subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Vessel puncture site haematoma subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0

Vessel puncture site swelling subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Xerosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Psychiatric disorders			
Abnormal behaviour subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	2 / 2014 (0.10%) 2	0 / 2040 (0.00%) 0
Abnormal dreams subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	0 / 2040 (0.00%) 0
Acute stress disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Adjustment disorder subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	2 / 2040 (0.10%) 2
Adjustment disorder with depressed mood subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	2 / 2014 (0.10%) 2	4 / 2040 (0.20%) 4
Affective disorder subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Agitation subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Anxiety subjects affected / exposed occurrences (all)	15 / 2014 (0.74%) 16	28 / 2014 (1.39%) 30	28 / 2040 (1.37%) 28
Anxiety disorder subjects affected / exposed occurrences (all)	3 / 2014 (0.15%) 3	8 / 2014 (0.40%) 8	8 / 2040 (0.39%) 8
Anxiety disorder due to a general medical condition			



subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Apathy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Bipolar disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Bruxism			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Compulsive hoarding			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	2	4	5
Daydreaming			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	41 / 2014 (2.04%)	83 / 2014 (4.12%)	80 / 2040 (3.92%)
occurrences (all)	43	93	93
Depressed mood			
subjects affected / exposed	3 / 2014 (0.15%)	12 / 2014 (0.60%)	8 / 2040 (0.39%)
occurrences (all)	3	12	8
Delirium			
subjects affected / exposed	2 / 2014 (0.10%)	8 / 2014 (0.40%)	3 / 2040 (0.15%)
occurrences (all)	2	8	3
Disorientation			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	0	3	3

Depressive symptom			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Drug use disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Emotional distress			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Feelings of worthlessness			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	1	3	2
Frustration tolerance decreased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Generalised anxiety disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	4 / 2040 (0.20%)
occurrences (all)	1	1	4
Grief reaction			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Hallucination			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	2	4	1
Hallucination, visual			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Hallucinations, mixed			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	36 / 2014 (1.79%)	74 / 2014 (3.67%)	57 / 2040 (2.79%)
occurrences (all)	38	81	61
Initial insomnia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Irritability			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Major depression			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	1	4	1
Mania			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Mental disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Mental status changes			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Middle insomnia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Mood altered			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Mood disorder due to a general medical condition			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Nervousness			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Nightmare			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	4 / 2014 (0.20%)	5 / 2014 (0.25%)	2 / 2040 (0.10%)
occurrences (all)	7	9	3
Panic disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1

Persistent depressive disorder subjects affected / exposed occurrences (all)	2 / 2014 (0.10%) 3	2 / 2014 (0.10%) 3	1 / 2040 (0.05%) 1
Pica subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Schizophrenia subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Senile psychosis subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Somatic symptom disorder subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Sleep disorder subjects affected / exposed occurrences (all)	8 / 2014 (0.40%) 8	12 / 2014 (0.60%) 12	8 / 2040 (0.39%) 8
Stress subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	3 / 2014 (0.15%) 3	1 / 2040 (0.05%) 1
Tension subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Reproductive system and breast disorders			
Adnexa uteri cyst subjects affected / exposed occurrences (all)	0 / 2014 (0.00%) 0	0 / 2014 (0.00%) 0	1 / 2040 (0.05%) 1
Atrophic vulvovaginitis subjects affected / exposed occurrences (all)	4 / 2014 (0.20%) 4	6 / 2014 (0.30%) 6	6 / 2040 (0.29%) 6
Breast calcifications subjects affected / exposed occurrences (all)	1 / 2014 (0.05%) 1	1 / 2014 (0.05%) 1	1 / 2040 (0.05%) 1
Breast cyst			

subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Breast discharge			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Breast disorder			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Breast enlargement			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Breast inflammation			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Breast haematoma			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Breast mass			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	1	2	3
Breast pain			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	2	4	5
Cervical dysplasia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cervical polyp			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Cervix inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Endometrial disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Cystocele			

subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences (all)	0	2	4
Endometrial hyperplasia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	2	0
Endometrial hypertrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Endometriosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Fallopian tube cyst			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Genital discharge			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Genital haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Genital pain			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Genital prolapse			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Genital tract inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Genital ulceration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Menopausal symptoms			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Metrorrhagia			

subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Nipple disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Ovarian cyst			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	6 / 2040 (0.29%)
occurrences (all)	2	3	6
Pelvic cyst			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	2 / 2014 (0.10%)	4 / 2014 (0.20%)	5 / 2040 (0.25%)
occurrences (all)	2	4	5
Perineal pain			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Rectocele			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Retracted nipple			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Uterine cyst			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Uterine haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Uterine polyp			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	0 / 2040 (0.00%)
occurrences (all)	3	5	0
Uterine prolapse			

subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	4	6	4
Vaginal discharge			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	1 / 2040 (0.05%)
occurrences (all)	1	2	1
Vaginal dysplasia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vaginal disorder			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2014 (0.00%)	3 / 2014 (0.15%)	6 / 2040 (0.29%)
occurrences (all)	0	3	6
Vaginal prolapse			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vaginal ulceration			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vulva cyst			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal burning sensation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Vulvovaginal dryness			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	1 / 2040 (0.05%)
occurrences (all)	3	4	1
Vulvovaginal pruritus			
subjects affected / exposed	4 / 2014 (0.20%)	6 / 2014 (0.30%)	3 / 2040 (0.15%)
occurrences (all)	4	7	3
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0



Allergic bronchitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	0	1	3
Allergic cough			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	6 / 2040 (0.29%)
occurrences (all)	0	1	6
Allergic respiratory disease			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	10 / 2014 (0.50%)	22 / 2014 (1.09%)	22 / 2040 (1.08%)
occurrences (all)	10	24	28
Allergic respiratory symptom			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Atelectasis			
subjects affected / exposed	6 / 2014 (0.30%)	11 / 2014 (0.55%)	1 / 2040 (0.05%)
occurrences (all)	6	11	1
Asthmatic crisis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	4	1
Bronchial obstruction			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Bronchial hyperreactivity			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Bronchiectasis			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	0	2	2
Bronchitis chronic			
subjects affected / exposed	6 / 2014 (0.30%)	17 / 2014 (0.84%)	8 / 2040 (0.39%)
occurrences (all)	6	18	8
Bronchospasm			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3

Catarrh			
subjects affected / exposed	3 / 2014 (0.15%)	5 / 2014 (0.25%)	9 / 2040 (0.44%)
occurrences (all)	4	6	10
Choking			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Chronic obstructive pulmonary disease			
subjects affected / exposed	24 / 2014 (1.19%)	49 / 2014 (2.43%)	35 / 2040 (1.72%)
occurrences (all)	30	66	60
Chronic respiratory failure			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	55 / 2014 (2.73%)	118 / 2014 (5.86%)	147 / 2040 (7.21%)
occurrences (all)	62	145	172
Dry throat			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Dysphonia			
subjects affected / exposed	7 / 2014 (0.35%)	12 / 2014 (0.60%)	8 / 2040 (0.39%)
occurrences (all)	7	12	9
Dyspnoea			
subjects affected / exposed	11 / 2014 (0.55%)	25 / 2014 (1.24%)	29 / 2040 (1.42%)
occurrences (all)	11	28	39
Dyspnoea exertional			
subjects affected / exposed	5 / 2014 (0.25%)	10 / 2014 (0.50%)	12 / 2040 (0.59%)
occurrences (all)	5	10	12
Epistaxis			
subjects affected / exposed	5 / 2014 (0.25%)	11 / 2014 (0.55%)	18 / 2040 (0.88%)
occurrences (all)	7	15	26
Emphysema			
subjects affected / exposed	3 / 2014 (0.15%)	7 / 2014 (0.35%)	6 / 2040 (0.29%)
occurrences (all)	3	7	6
Haemoptysis			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	3 / 2040 (0.15%)

occurrences (all)	2	3	3
Hiccups			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	2
Hydrothorax			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Hypoventilation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Idiopathic pulmonary fibrosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Increased upper airway secretion			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	3	0
Laryngeal oedema			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Interstitial lung disease			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Laryngitis allergic			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	3
Lung disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	1	1	2
Nasal congestion			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)

occurrences (all)	1	1	3
Lung hyperinflation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Nasal discomfort			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Nasal dryness			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Nasal inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Nasal mucosal hypertrophy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Nasal polyps			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Nasal pruritus			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Nasal septum deviation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Obstructive airways disorder			
subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	4 / 2040 (0.20%)
occurrences (all)	0	2	4
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Oropharyngeal pain			
subjects affected / exposed	8 / 2014 (0.40%)	18 / 2014 (0.89%)	16 / 2040 (0.78%)
occurrences (all)	9	19	17
Pharyngeal inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)

occurrences (all)	0	1	2
Pharyngeal ulceration			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Pleural adhesion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pleural calcification			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Pleural effusion			
subjects affected / exposed	3 / 2014 (0.15%)	13 / 2014 (0.65%)	4 / 2040 (0.20%)
occurrences (all)	3	13	5
Pleural thickening			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Pleurisy			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Pneumonia aspiration			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Pneumonitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	3	1
Productive cough			
subjects affected / exposed	9 / 2014 (0.45%)	11 / 2014 (0.55%)	16 / 2040 (0.78%)
occurrences (all)	10	12	17
Pulmonary arterial hypertension			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1
Pulmonary calcification			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	1	2	0
Pulmonary congestion			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)

occurrences (all)	1	1	0
Pulmonary embolism			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Pulmonary fibrosis			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	2 / 2040 (0.10%)
occurrences (all)	1	2	2
Pulmonary granuloma			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Pulmonary hypertension			
subjects affected / exposed	3 / 2014 (0.15%)	21 / 2014 (1.04%)	12 / 2040 (0.59%)
occurrences (all)	3	21	12
Pulmonary infarction			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pulmonary mass			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	2 / 2040 (0.10%)
occurrences (all)	2	3	2
Pulmonary oedema			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Rales			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Pulmonary vascular disorder			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Respiratory disorder			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	3 / 2040 (0.15%)
occurrences (all)	1	1	4
Respiratory alkalosis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Respiratory distress			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	3 / 2040 (0.15%)

occurrences (all)	0	0	3
Respiratory tract congestion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	1 / 2014 (0.05%)	2 / 2014 (0.10%)	7 / 2040 (0.34%)
occurrences (all)	1	2	7
Rhinitis allergic			
subjects affected / exposed	7 / 2014 (0.35%)	14 / 2014 (0.70%)	15 / 2040 (0.74%)
occurrences (all)	7	14	18
Sinus congestion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Sleep apnoea syndrome			
subjects affected / exposed	1 / 2014 (0.05%)	3 / 2014 (0.15%)	4 / 2040 (0.20%)
occurrences (all)	1	3	4
Sputum increased			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	2 / 2040 (0.10%)
occurrences (all)	0	0	2
Tonsillar cyst			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Throat irritation			
subjects affected / exposed	2 / 2014 (0.10%)	3 / 2014 (0.15%)	1 / 2040 (0.05%)
occurrences (all)	2	3	1
Upper respiratory tract congestion			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	2	2	3
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Vocal cord cyst			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)

occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	2 / 2014 (0.10%)	2 / 2014 (0.10%)	0 / 2040 (0.00%)
occurrences (all)	2	2	0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Biliary colic			
subjects affected / exposed	4 / 2014 (0.20%)	4 / 2014 (0.20%)	4 / 2040 (0.20%)
occurrences (all)	4	4	4
Bile duct stone			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Biliary dilatation			
subjects affected / exposed	3 / 2014 (0.15%)	4 / 2014 (0.20%)	2 / 2040 (0.10%)
occurrences (all)	3	4	2
Cholangitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Cholecystitis			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	3
Cholecystitis acute			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Cholecystitis chronic			
subjects affected / exposed	5 / 2014 (0.25%)	7 / 2014 (0.35%)	2 / 2040 (0.10%)
occurrences (all)	5	7	2
Cholelithiasis			
subjects affected / exposed	12 / 2014 (0.60%)	28 / 2014 (1.39%)	22 / 2040 (1.08%)
occurrences (all)	12	29	22
Drug-induced liver injury			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Gallbladder polyp			



subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Granulomatous liver disease			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	0	1	1
Hepatic atrophy			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hepatic cirrhosis			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hepatic cyst			
subjects affected / exposed	4 / 2014 (0.20%)	9 / 2014 (0.45%)	17 / 2040 (0.83%)
occurrences (all)	4	9	17
Hepatic function abnormal			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hepatic steatosis			
subjects affected / exposed	6 / 2014 (0.30%)	21 / 2014 (1.04%)	12 / 2040 (0.59%)
occurrences (all)	6	21	12
Hepatic lesion			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	2 / 2040 (0.10%)
occurrences (all)	0	1	2
Hepatitis			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	1	1	0
Hepatobiliary disease			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Hypertransaminasaemia			
subjects affected / exposed	0 / 2014 (0.00%)	0 / 2014 (0.00%)	1 / 2040 (0.05%)
occurrences (all)	0	0	1
Jaundice			
subjects affected / exposed	0 / 2014 (0.00%)	1 / 2014 (0.05%)	0 / 2040 (0.00%)
occurrences (all)	0	1	0
Liver disorder			

subjects affected / exposed	0 / 2014 (0.00%)	2 / 2014 (0.10%)	3 / 2040 (0.15%)
occurrences (all)	0	2	3
Liver injury			
subjects affected / exposed	1 / 2014 (0.05%)	1 / 2014 (0.05%)	1 / 2040 (0.05%)
occurrences (all)	1	1	1

<b>Non-serious adverse events</b>	12-Month Double-blind Period: Romosozumab 210 mg QM		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1492 / 2040 (73.14%)		
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Abdominal wound dehiscence			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Accident			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Accident at home			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Accidental exposure to product			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Accidental overdose			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Acetabulum fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anaemia postoperative			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		

Animal bite			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Arterial injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	6		
Arthropod sting			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Back injury			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Bladder injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bone contusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Brain contusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Burns first degree			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Burns second degree			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Chemical burn of skin			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Chemical cystitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Chemical poisoning subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Chest injury subjects affected / exposed occurrences (all)	4 / 2040 (0.20%) 4		
Chillblains subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Clavicle fracture subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Commotio retinae subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Concussion subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Confusion postoperative subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Contusion subjects affected / exposed occurrences (all)	51 / 2040 (2.50%) 58		
Corneal abrasion subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Craniocerebral injury subjects affected / exposed occurrences (all)	5 / 2040 (0.25%) 5		
Deep vein thrombosis postoperative subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Dislocation of vertebra subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		

Ear canal injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ear canal abrasion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ear injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Epicondylitis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Epidural haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Excoriation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eye contusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eye injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eyelid contusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Face injury			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	5		
Facial bones fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	127 / 2040 (6.23%)		
occurrences (all)	165		

Fat overload syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Femoral neck fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Femur fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Fibula fracture			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Foot fracture			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Foreign body			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Foreign body in eye			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Fracture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Fractured ischium			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Fractured sacrum			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gastrointestinal injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Frostbite			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Gingival injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hand fracture			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Head injury			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Heart injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Humerus fracture			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Iliotibial band syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ilium fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Incisional hernia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Injury			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Jaw fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Joint dislocation			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Joint injury			
subjects affected / exposed	16 / 2040 (0.78%)		
occurrences (all)	17		

Laceration			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	10		
Ligament injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ligament rupture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Ligament sprain			
subjects affected / exposed	13 / 2040 (0.64%)		
occurrences (all)	13		
Limb crushing injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	19 / 2040 (0.93%)		
occurrences (all)	20		
Lumbar vertebral fracture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lip injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Meniscus injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Multiple injuries			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Muscle injury			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Muscle rupture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		



Muscle strain			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Nasal injury			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Neck injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Overdose			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Patella fracture			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Pelvic organ injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Perineal injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Periorbital haematoma			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Periorbital haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral nerve injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Post concussion syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Post procedural complication			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Post procedural fistula subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Post procedural oedema subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Post procedural hypothyroidism subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Post procedural swelling subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Post-traumatic neck syndrome subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Post-traumatic pain subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Postoperative fever subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Procedural complication subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Procedural pain subjects affected / exposed occurrences (all)	7 / 2040 (0.34%) 8		
Procedural nausea subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Pubis fracture subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		

Radiation associated pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Radiation leukopenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Radius fracture			
subjects affected / exposed	22 / 2040 (1.08%)		
occurrences (all)	22		
Respiratory fume inhalation disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Road traffic accident			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Rib fracture			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Scar			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Seroma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Scratch			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	9		
Skeletal injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Skin wound			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skull fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Soft tissue injury			
subjects affected / exposed	23 / 2040 (1.13%)		
occurrences (all)	27		
Spinal column injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Spinal compression fracture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Spinal fracture			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Sternal fracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Stoma obstruction			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Subcutaneous haematoma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Subdural haematoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sunburn			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Synovial rupture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Tendon injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tendon rupture			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	5		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tibia fracture			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Thermal burn			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Tongue injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tooth injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tooth avulsion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Toxicity to various agents			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Transfusion reaction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Traumatic haematoma			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		

Traumatic haemothorax subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Traumatic lung injury subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Vaccination complication subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Ulna fracture subjects affected / exposed occurrences (all)	14 / 2040 (0.69%) 14		
Vaginal laceration subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Vascular injury subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Wound haemorrhage subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Vascular pseudoaneurysm subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Wound subjects affected / exposed occurrences (all)	9 / 2040 (0.44%) 9		
Wound secretion subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Wrist fracture subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Investigations Alanine aminotransferase increased subjects affected / exposed	2 / 2040 (0.10%)		

occurrences (all)	2		
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aortic bruit			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Aspiration joint			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood bilirubin increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood calcium increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood cholesterol abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood cholesterol increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood chloride decreased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood creatine increased			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood glucose abnormal			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Blood glucose increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood folate decreased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood magnesium decreased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood potassium abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood potassium decreased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Blood pressure abnormal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood potassium increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood pressure ambulatory			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood pressure decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood pressure diastolic increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood sodium decreased			



subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Blood pressure increased			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Blood urea increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood triglycerides increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Body mass index increased			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Blood uric acid increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Body height decreased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Bone density abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Body temperature increased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Bone density decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Brain scan abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Carcinoembryonic antigen increased subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Cardiac function test abnormal subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
C-reactive protein increased subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Computerised tomogram head abnormal subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Chest X-ray abnormal subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Cardiac murmur subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Creatinine renal clearance decreased subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Electrocardiogram repolarisation abnormality subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Fibrin D dimer increased subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Escherichia test positive subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Glomerular filtration rate increased subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Glomerular filtration rate decreased			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	5		
Haemoglobin			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Haemoglobin abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Haemoglobin increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Heart rate increased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Heart rate irregular			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Hepatic enzyme increased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Inflammatory marker increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
International normalised ratio decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
International normalised ratio increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Intestinal transit time decreased			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Intraocular pressure increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Klebsiella test positive			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Liver function test abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Liver function test increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Low density lipoprotein increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lymphocyte count increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Mycoplasma test positive			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Monocyte count increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Neutrophil count decreased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		
Nuclear magnetic resonance imaging brain abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Occult blood positive			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Occult blood			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oxygen saturation decreased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Platelet count decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Renal function test abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Staphylococcus test positive			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Thyroxine increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Transaminases increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Ultrasound liver abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ultrasound uterus abnormal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Urine analysis abnormal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urine output increased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Vitamin D decreased subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Weight decreased subjects affected / exposed occurrences (all)	14 / 2040 (0.69%) 14		
Weight increased subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
White blood cell count decreased subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Cardiac disorders			
Acute coronary syndrome subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Acute myocardial infarction subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Angina pectoris subjects affected / exposed occurrences (all)	8 / 2040 (0.39%) 8		
Angina unstable subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Aortic valve calcification subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Aortic valve disease mixed subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Aortic valve incompetence subjects affected / exposed	9 / 2040 (0.44%)		

occurrences (all)	9		
Aortic valve sclerosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aortic valve stenosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Arrhythmia			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Arrhythmia supraventricular			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Arteriosclerosis coronary artery			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Atrial fibrillation			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Atrial flutter			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Atrial tachycardia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Atrioventricular block			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Atrioventricular block complete			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Atrioventricular block first degree			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Atrioventricular block second degree			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Bradycardia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bundle branch block			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bundle branch block left			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bundle branch block right			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cardiac discomfort			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cardiac failure			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Cardiac failure chronic			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Cardiac failure congestive			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cardiac hypertrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cardiac septal hypertrophy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cardiac valve disease			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cardiac valve sclerosis			
subjects affected / exposed	0 / 2040 (0.00%)		



occurrences (all)	0		
Cardiomegaly			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Cardiomyopathy			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Cardiovascular disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Cardiovascular insufficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Conduction disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Congestive cardiomyopathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Coronary artery disease			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Coronary artery stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Defect conduction intraventricular			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Degenerative aortic valve disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Degenerative mitral valve disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Diastolic dysfunction			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Dilatation atrial			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Dilatation ventricular			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Extrasystoles			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Heart valve incompetence			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypertensive heart disease			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Left atrial dilatation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Left atrial enlargement			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Left atrial hypertrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Left ventricular dilatation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Left ventricular dysfunction			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Left ventricular failure			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Left ventricular hypertrophy			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Mitral valve disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mitral valve incompetence			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	11		
Mitral valve prolapse			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mitral valve sclerosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Mitral valve stenosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Myocardial fibrosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Myocardial infarction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Myocardial ischaemia			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Nodal rhythm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Pericardial effusion			
subjects affected / exposed	3 / 2040 (0.15%)		

occurrences (all)	3		
Postinfarction angina			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary valve incompetence			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Right atrial dilatation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Right ventricular failure			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Sinus bradycardia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Sinus node dysfunction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Supraventricular extrasystoles			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Supraventricular tachycardia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Systolic dysfunction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tachyarrhythmia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	5 / 2040 (0.25%)		

occurrences (all)	6		
Tricuspid valve incompetence subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Ventricular arrhythmia subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Ventricular extrasystoles subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Ventricular fibrillation subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Ventricular tachycardia subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Biliary hamartoma subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Congenital cerebrovascular anomaly subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Congenital cystic kidney disease subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Congenital hypercoagulation subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Corneal dystrophy subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypertrophic cardiomyopathy subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Muscular dystrophy subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Odontogenic cyst subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Thalassaemia subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Tuberous sclerosis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Vertebral artery hypoplasia subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	41 / 2040 (2.01%) 43		
Anaemia megaloblastic subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Anaemia of chronic disease subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Anaemia vitamin B12 deficiency subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Anaemia vitamin B6 deficiency subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Bicytopenia subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Eosinophilia subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Granulocytopenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Haemoconcentration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Haemorrhagic anaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hyperchromic anaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypochromic anaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Increased tendency to bruise			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Leukocytosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Leukopenia			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	6		
Lymph node pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Lymphocytosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Lymphopenia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Microcytic anaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Neutrophilia			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pancytopenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pernicious anaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Purpura non-thrombocytopenic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retroperitoneal lymphadenopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Thrombocytosis			
subjects affected / exposed	4 / 2040 (0.20%)		



occurrences (all)	5		
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Nervous system disorders			
Amnesia			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Amnestic disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Amputation stump pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anticholinergic syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aphasia			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Ataxia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Balance disorder			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aura			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Brain oedema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Brain injury			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		

Carotid artery stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Carotid arteriosclerosis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Burning sensation			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Carpal tunnel syndrome			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Central nervous system necrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Central nervous system lesion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cerebellar atrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral amyloid angiopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral artery embolism			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral arteriosclerosis			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Cerebral atrophy			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Cerebral calcification			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Cerebral artery stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral circulatory failure			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cerebral haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral hypoperfusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral haematoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral ischaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral infarction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebral ventricle dilatation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cerebral microangiopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebrosclerosis			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Cerebrovascular accident			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cerebrovascular insufficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cerebrovascular disorder			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Cervical radiculopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cervicobrachial syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Circadian rhythm sleep disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cognitive disorder			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Coma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Dementia			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Dementia Alzheimer's type			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Diabetic neuropathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Disturbance in attention			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Dizziness			
subjects affected / exposed	85 / 2040 (4.17%)		
occurrences (all)	100		
Dizziness postural			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Dysaesthesia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Dysarthria			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dysgeusia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Dyskinesia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Encephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Encephalomalacia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Epidural lipomatosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Essential tremor			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Epilepsy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Facial neuralgia			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Facial paralysis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gliositis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Haemorrhagic stroke			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	106 / 2040 (5.20%)		
occurrences (all)	128		
Hydrocephalus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hemiparesis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypersomnia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	13		
Hypertensive encephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypotonia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypokinesia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
IIIrd nerve paralysis			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Incoherent			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Intention tremor			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Intercostal neuralgia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Intracranial aneurysm			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Intracranial haematoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ischaemic stroke			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lacunar infarction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Lacunar stroke			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Loss of consciousness			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Leukoencephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lumbar radiculopathy			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Memory impairment			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	12		
Lumbosacral radiculopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Metabolic encephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Monoparesis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Multiple sclerosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Muscle contractions involuntary			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Muscle spasticity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Myoclonus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nerve root compression			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nervous system disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nerve compression			
subjects affected / exposed	0 / 2040 (0.00%)		



occurrences (all)	0		
Neuralgia			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Neuralgic amyotrophy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Neuritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Neurodegenerative disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	5		
Nystagmus			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Occipital neuralgia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Notalgia paraesthetica			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Paresis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Parkinson's disease			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Paraesthesia			
subjects affected / exposed	28 / 2040 (1.37%)		
occurrences (all)	30		
Parkinsonism			
subjects affected / exposed	2 / 2040 (0.10%)		

occurrences (all)	2		
Partial seizures			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Parosmia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral nerve lesion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Petit mal epilepsy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peroneal nerve palsy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Polyneuropathy			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Post herpetic neuralgia			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Polyneuropathy alcoholic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Poor quality sleep			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Presyncope			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Post-traumatic headache			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rabbit syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Radicular pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Radicular syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Radiculopathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Restless legs syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	24 / 2040 (1.18%)		
occurrences (all)	29		
Seizure			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Senile dementia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Seizure anoxic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sinus headache			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Sensory disturbance			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Speech disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Spinal claudication			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Spinal cord disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Spinal meningeal cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Subdural effusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Stroke in evolution			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	13 / 2040 (0.64%)		
occurrences (all)	17		
Tension headache			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Tremor			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Transient ischaemic attack			
subjects affected / exposed	3 / 2040 (0.15%)		

occurrences (all)	3		
Trigeminal nerve disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Trigeminal neuritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Trigeminal neuralgia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Ulnar neuritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vlth nerve disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Unresponsive to stimuli			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vascular dementia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vascular encephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vertebral artery stenosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vertebrobasilar insufficiency			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Vocal cord paresis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
White matter lesion			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
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Eye disorders			
Age-related macular degeneration			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Amblyopia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Amaurosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anisometropia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Asthenopia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Anterior capsule contraction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Astigmatism			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blepharitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Blepharochalasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blepharospasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cataract			
subjects affected / exposed	46 / 2040 (2.25%)		
occurrences (all)	51		

Chalazion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Cataract nuclear			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Conjunctival oedema			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Conjunctival irritation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Corneal degeneration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Conjunctivitis allergic			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Corneal disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Corneal erosion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Corneal opacity			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cystoid macular oedema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dacryostenosis acquired			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Diabetic retinopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Diplopia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eczema eyelids			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Endocrine ophthalmopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Episcleritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Exfoliation glaucoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eye allergy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eye degenerative disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eye inflammation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eye haemorrhage			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eye irritation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		



Eye pain			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Eye pruritus			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Eye swelling			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eye ulcer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eyelid cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eyelid dermatochalasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eyelid disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eyelid pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eyelid ptosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Foreign body sensation in eyes			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Glaucoma			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		

Hypermetropia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Iridocyclitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Iritis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Keratitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Keratopathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lacrimal disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lacrimal structural disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lacrimation decreased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Lacrimation increased			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Macular degeneration			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Macular fibrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Macular hole			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Maculopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Myopia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Narrow anterior chamber angle			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ocular discomfort			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Ocular hyperaemia			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Open angle glaucoma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Optic disc disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Periorbital oedema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Posterior capsule opacification			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Photopsia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Presbyopia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pterygium			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Refraction disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retinal degeneration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retinal detachment			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retinal haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retinal vascular disorder			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Retinal tear			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retinal vascular occlusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retinal vein occlusion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Retinal vein thrombosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Retinopathy hypertensive			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Retinopathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Strabismus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Ulcerative keratitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Trichiasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Uveitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vision blurred			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	5		
Visual acuity reduced			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Vitreous adhesions			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vitreous degeneration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vitreous detachment			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vitreous disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vitreous floaters			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vitreous haemorrhage			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		

Xerophthalmia subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Ear and labyrinth disorders			
Acute vestibular syndrome subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Cerumen impaction subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Cupulolithiasis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Deafness bilateral subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Ear canal erythema subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Ear discomfort subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Ear disorder subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Ear pain subjects affected / exposed occurrences (all)	4 / 2040 (0.20%) 4		
Ear pruritus subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Excessive cerumen production subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Hypoacusis subjects affected / exposed	10 / 2040 (0.49%)		

occurrences (all)	10		
Inner ear disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Meniere's disease			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Motion sickness			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Neurosensory hypoacusis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Presbycusis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tinnitus			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	12		
Tympanic membrane perforation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	41 / 2040 (2.01%)		
occurrences (all)	50		
Vertigo positional			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	5		
Vestibular ataxia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vestibular disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Abdominal adhesions			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Abdominal hernia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Abdominal mass			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	38 / 2040 (1.86%)		
occurrences (all)	40		
Abdominal pain lower			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Abdominal pain upper			
subjects affected / exposed	62 / 2040 (3.04%)		
occurrences (all)	63		
Abdominal rigidity			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Abdominal symptom			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Abnormal faeces			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Acid peptic disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		



Anal haemorrhage			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Anal incontinence			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Anal prolapse			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anal pruritus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anal sphincter atony			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anal ulcer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anorectal disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Anorectal varices			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aphthous ulcer			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	7		
Apical granuloma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Aptyalism			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Barrett's oesophagus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Breath odour			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Change of bowel habit			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cheilitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Chronic gastritis			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Coeliac disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Colitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Colitis erosive			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Colitis psychogenic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Colitis ischaemic			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Colitis ulcerative			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	75 / 2040 (3.68%)		
occurrences (all)	79		
Dental caries			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	11		

Diaphragmatic hernia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	99 / 2040 (4.85%)		
occurrences (all)	111		
Diverticulum			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Diverticulum intestinal			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Dry mouth			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Duodenal polyp			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Duodenitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Duodenal ulcer			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Duodenogastric reflux			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	52 / 2040 (2.55%)		
occurrences (all)	56		
Dysphagia			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Enteritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Enterocolitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Epigastric discomfort			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Erosive oesophagitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Erosive duodenitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eructation			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Faeces discoloured			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Food poisoning			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Flatulence			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Frequent bowel movements			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gastric disorder			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Gastric antral vascular ectasia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gastric mucosa erythema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		

Gastric mucosal hypertrophy subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastric polyps subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gastric ulcer subjects affected / exposed occurrences (all)	3 / 2040 (0.15%) 3		
Gastric ulcer haemorrhage subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastritis subjects affected / exposed occurrences (all)	53 / 2040 (2.60%) 60		
Gastritis erosive subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Gastritis haemorrhagic subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastroduodenal ulcer subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastroduodenitis subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gastrointestinal angiectasia subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastrointestinal disorder subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastrointestinal fistula subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		

Gastrointestinal haemorrhage subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Gastrointestinal hypermotility subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gastrointestinal inflammation subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastrointestinal motility disorder subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gastrointestinal mucosal disorder subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastrointestinal pain subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastrointestinal obstruction subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gastrointestinal sounds abnormal subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gastrointestinal tract irritation subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Gastrointestinal wall thickening subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	29 / 2040 (1.42%) 29		
Gingival atrophy subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		

Gastrooesophageal sphincter insufficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gingival bleeding			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gingival disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gingival erythema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gingival hypertrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gingival pain			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Gingival recession			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gingival swelling			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Glossitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Haematemesis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Haematochezia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Haemorrhagic erosive gastritis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Haemorrhoidal haemorrhage			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Haemorrhoids			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		
Hernial eventration			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hiatus hernia			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	11		
Hyperchlorhydria			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypoaesthesia oral			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypoaesthesia teeth			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ileus			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Inguinal hernia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Intestinal metaplasia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Intestinal polyp			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		



Irritable bowel syndrome			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	11		
Large intestinal stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Large intestine polyp			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Lip discolouration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lip haematoma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lip swelling			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Loose tooth			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Malabsorption			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Melaena			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Mouth swelling			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Mouth ulceration			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		

Nausea			
subjects affected / exposed	38 / 2040 (1.86%)		
occurrences (all)	45		
Noninfective gingivitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Noninfective sialoadenitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Obstruction gastric			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Odynophagia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Oesophageal disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oesophageal polyp			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oesophageal stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oesophageal ulcer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oesophagitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Oral contusion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oral discomfort			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Oral disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oral mucosal discolouration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pancreatic cyst			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pancreatic disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pancreatitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pancreatitis chronic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peptic ulcer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Periodontal disease			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Periodontal inflammation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Peritoneal adhesions			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pharyngo-oesophageal diverticulum			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Presbyoesophagus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Proctalgia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Proctitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Rectal polyp			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rectal prolapse			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Reflux gastritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Salivary gland calculus			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Salivary gland enlargement			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Salivary gland mass			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Salivary hypersecretion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sensitivity of teeth			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Short-bowel syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Stomatitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Swollen tongue			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tongue coated			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tongue discolouration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tongue discomfort			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tongue disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tongue ulceration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tooth discolouration			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tooth disorder			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Tooth impacted			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Tooth loss			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Toothache			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	11		

Umbilical hernia			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Varices oesophageal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Varicose veins of abdominal wall			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	23 / 2040 (1.13%)		
occurrences (all)	28		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bladder dysfunction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bladder pain			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bladder prolapse			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bladder perforation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Calculus urinary			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Bladder spasm			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Costovertebral angle tenderness			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Chronic kidney disease			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Cystitis haemorrhagic			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Cystitis noninfective			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		
Haematuria			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Hydronephrosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hydroureter			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypertonic bladder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Incontinence			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Kidney enlargement			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Leukocyturia			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Kidney fibrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Micturition urgency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nephritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nephroangiosclerosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nephrolithiasis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Nephropathy			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Nephroptosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Nephrosclerosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nocturia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Oliguria			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Pollakiuria			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Polyuria			
subjects affected / exposed	5 / 2040 (0.25%)		



occurrences (all)	5		
Proteinuria			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Pyelocaliectasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Renal atrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Renal colic			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Renal cyst			
subjects affected / exposed	13 / 2040 (0.64%)		
occurrences (all)	14		
Renal disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Renal failure			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	5		
Renal impairment			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Renal injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Renal pain			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Renal vein thrombosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Stress urinary incontinence			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Ureteric dilatation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urge incontinence			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urinary bladder haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Urinary retention			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Urinary tract disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Urinary tract inflammation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Urine abnormality			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Urine odour abnormal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Product issues			
Device breakage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Device failure			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Device loosening			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Actinic keratosis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Alopecia			
subjects affected / exposed	18 / 2040 (0.88%)		
occurrences (all)	18		
Alopecia areata			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Angioedema			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Blister			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Decubitus ulcer			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Dermal cyst			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Dermatitis			
subjects affected / exposed	17 / 2040 (0.83%)		
occurrences (all)	18		
Dermatitis acneiform			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Dermatitis allergic			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	16		

Dermatitis atopic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Dermatitis diaper			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dermatitis psoriasiform			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Diabetic foot			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Drug eruption			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		
Dry skin			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Ecchymosis			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Eczema			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	10		
Eczema nummular			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	6		
Generalised erythema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Haemorrhage subcutaneous subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hair growth abnormal subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hair texture abnormal subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hand dermatitis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hyperhidrosis subjects affected / exposed occurrences (all)	3 / 2040 (0.15%) 3		
Hyperkeratosis subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Hypertrichosis subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Hypertrophic scar subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Ingrowing nail subjects affected / exposed occurrences (all)	3 / 2040 (0.15%) 3		
Lichen sclerosus subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Intertrigo subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Lichen planus subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		

Melanosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Macule			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lichenoid keratosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Nail discomfort			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nail atrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nail psoriasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nail ridging			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nail disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Onychoclasia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Night sweats			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Neurodermatitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Onychomadesis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Onycholysis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pain of skin			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Panniculitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Papule			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pemphigus			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pemphigoid			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Prurigo			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Petechiae			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pigmentation disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	14		
Pruritus allergic			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Pruritus generalised			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	10		

Psoriasis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Rash			
subjects affected / exposed	22 / 2040 (1.08%)		
occurrences (all)	25		
Rash erythematous			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rash generalised			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Rash maculo-papular			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Rash macular			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Rash papular			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Rash papulosquamous			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	13 / 2040 (0.64%)		
occurrences (all)	15		
Rash vesicular			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rosacea			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Seborrhoea			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		



Seborrhoeic dermatitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Skin atrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin burning sensation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin discolouration			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Skin disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Skin exfoliation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Skin fissures			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin hypopigmentation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Skin induration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin irritation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin mass			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Skin lesion			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	12		

Skin necrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin plaque			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Skin ulcer			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	11		
Skin ulcer haemorrhage			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Solar dermatitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Solar lentigo			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Stasis dermatitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Swelling face			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Telangiectasia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Toxic skin eruption			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Umbilical discharge			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		

Urticaria chronic subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Vascular purpura subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Xeroderma subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	165 / 2040 (8.09%) 198		
Arthritis subjects affected / exposed occurrences (all)	3 / 2040 (0.15%) 3		
Arthritis reactive subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Arthropathy subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Autoimmune arthritis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Axillary mass subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Back pain subjects affected / exposed occurrences (all)	184 / 2040 (9.02%) 205		
Bone cyst subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Bone deformity subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Bone disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bone loss			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bone lesion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bone swelling			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	12		
Cervical spinal stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bursitis			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	7		
Chondrocalcinosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Coccydynia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Costochondritis			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Deformity thorax			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Dupuytren's contracture			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Enostosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Enthesopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Exostosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Femoroacetabular impingement			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Fibromyalgia			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Finger deformity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		
Foot deformity			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Fracture pain			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	12		
Gouty arthritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	4 / 2040 (0.20%)		

occurrences (all)	4		
Haemarthrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hand deformity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypercreatinaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Interspinous osteoarthritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Intervertebral disc degeneration			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Intervertebral disc disorder			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Intervertebral disc protrusion			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Intervertebral disc space narrowing			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Joint ankylosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Joint crepitation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Joint effusion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Joint instability			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Joint lock			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Joint range of motion decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Joint stiffness			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Joint swelling			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	12		
Kyphosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Ligamentitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Limb deformity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Limb discomfort			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	3		
Loose body in joint			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lordosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lumbar spinal stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Metatarsalgia			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Mobility decreased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Muscle atrophy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Muscle contracture			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Muscle disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Muscle fatigue			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	70 / 2040 (3.43%)		
occurrences (all)	73		
Muscle tightness			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Muscle twitching			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Musculoskeletal chest pain			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		
Muscular weakness			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	16		
Musculoskeletal discomfort			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Musculoskeletal pain			
subjects affected / exposed	70 / 2040 (3.43%)		



occurrences (all)	78		
Musculoskeletal stiffness			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Myalgia			
subjects affected / exposed	56 / 2040 (2.75%)		
occurrences (all)	58		
Myofascial pain syndrome			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Myositis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Neck deformity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Osteitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	34 / 2040 (1.67%)		
occurrences (all)	34		
Neck mass			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Osteolysis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Osteoarthritis			
subjects affected / exposed	113 / 2040 (5.54%)		
occurrences (all)	131		
Osteochondrosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Osteoporosis			
subjects affected / exposed	2 / 2040 (0.10%)		

occurrences (all)	2		
Osteonecrosis of jaw			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Osteosclerosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Pain in extremity			
subjects affected / exposed	121 / 2040 (5.93%)		
occurrences (all)	138		
Pain in jaw			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Periarthritis			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Polyarthrititis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Plantar fasciitis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Periostitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Polymyalgia rheumatica			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Rheumatoid arthritis			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	6		
Sacroiliitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rotator cuff syndrome			
subjects affected / exposed	5 / 2040 (0.25%)		

occurrences (all)	7		
Scoliosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Seronegative arthritis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Sjogren's syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Soft tissue disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Spinal column stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Soft tissue mass			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Spinal osteoarthritis			
subjects affected / exposed	23 / 2040 (1.13%)		
occurrences (all)	23		
Spinal disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Spinal deformity			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Spondylitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Spondyloarthropathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Spinal pain			
subjects affected / exposed	29 / 2040 (1.42%)		

occurrences (all)	30		
Spondylolisthesis			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Spondylolysis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sympathetic posterior cervical syndrome			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Synovial cyst			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Synovitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Systemic lupus erythematosus			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tendon disorder			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	5		
Tendon pain			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tendonitis			
subjects affected / exposed	13 / 2040 (0.64%)		
occurrences (all)	16		
Tenosynovitis stenosans			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tenosynovitis			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Trismus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Torticollis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Trigger finger			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vertebral wedging			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Adrenal disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Adrenal insufficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Adrenal mass			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Empty sella syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Autoimmune thyroiditis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Goitre			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		

Hypercorticism			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hyperparathyroidism			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hyperparathyroidism primary			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hyperparathyroidism secondary			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hyperthyroidism			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	12		
Hypothyroidism			
subjects affected / exposed	18 / 2040 (0.88%)		
occurrences (all)	18		
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Thyroid cyst			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Thyroid disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Thyroid mass			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Thyroiditis chronic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Toxic goitre			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Toxic nodular goitre subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Metabolism and nutrition disorders			
Abnormal loss of weight subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Acquired mixed hyperlipidaemia subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Carbohydrate intolerance subjects affected / exposed occurrences (all)	3 / 2040 (0.15%) 3		
Calcium metabolism disorder subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Decreased appetite subjects affected / exposed occurrences (all)	22 / 2040 (1.08%) 23		
Dehydration subjects affected / exposed occurrences (all)	4 / 2040 (0.20%) 4		
Diabetes mellitus subjects affected / exposed occurrences (all)	14 / 2040 (0.69%) 15		
Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Dyslipidaemia subjects affected / exposed occurrences (all)	23 / 2040 (1.13%) 23		
Fluid overload subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Electrolyte imbalance subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Fluid retention			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Folate deficiency			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Food intolerance			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Glucose tolerance impaired			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Gluten sensitivity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Hyperammonaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Hypercholesterolaemia			
subjects affected / exposed	26 / 2040 (1.27%)		
occurrences (all)	26		
Hyperhomocysteinaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	11		
Hyperlipidaemia			
subjects affected / exposed	5 / 2040 (0.25%)		



occurrences (all)	5		
Hyperkalaemia			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Hypermagnesaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypernatraemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hyperphagia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypertriglyceridaemia			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Hyperuricaemia			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	10		
Hyperphosphataemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypervitaminosis D			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypochloraemia			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Hypocalcaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	6 / 2040 (0.29%)		

occurrences (all)	7		
Hypomagnesaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		
Hypophosphataemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	14		
Hypoproteinaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypovitaminosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypovolaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Impaired fasting glucose			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Increased appetite			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Iron deficiency			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lipid metabolism disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Metabolic acidosis			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Malnutrition			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Metabolic disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mineral deficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Obesity			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Polydipsia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Underweight			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vitamin B complex deficiency			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vitamin B12 deficiency			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Vitamin D deficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Abscess limb			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Abscess oral			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Acarodermatitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Acute sinusitis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Amoebic dysentery			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Angular cheilitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Appendiceal abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Appendicitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Arthritis bacterial			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Arthritis infective			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Atypical pneumonia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bacterial diarrhoea			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bacterial infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bacterial tracheitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bacterial vaginosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bacterial vulvovaginitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bacteriuria			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bartholin's abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Body tinea			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Borrelia infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	88 / 2040 (4.31%)		
occurrences (all)	97		
Bronchitis bacterial			

subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	7		
Bronchitis viral			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Candida infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Carbuncle			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	14		
Cellulitis staphylococcal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cervicitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Chikungunya virus infection			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Chronic sinusitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Chronic tonsillitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Clostridium difficile colitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Clostridium difficile infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Conjunctivitis			

subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		
Conjunctivitis bacterial			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Conjunctivitis viral			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Corneal infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	25 / 2040 (1.23%)		
occurrences (all)	31		
Cystitis bacterial			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Dacryocanaliculitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dacryocystitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dengue fever			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Dermatitis infected			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dermatophytosis of nail			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Dermo-hypodermatitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Diarrhoea infectious			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Diverticulitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Ear infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ear infection bacterial			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Ear infection fungal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Ear infection viral			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Enterobiasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Enterococcal infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Enterocolitis viral			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Erysipelas			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Escherichia urinary tract infection			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Eye infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eye infection bacterial			



subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eyelid infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Flavivirus infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Febrile infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Fungal infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Fungal skin infection			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Folliculitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Furuncle			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Gastritis bacterial			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	36 / 2040 (1.76%)		
occurrences (all)	38		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gastroenteritis bacterial			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			

subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	12		
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gastrointestinal fungal infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Gastrointestinal infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Gastrointestinal viral infection			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Genital candidiasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Genital herpes			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		
Genital herpes zoster			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Genital infection fungal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Genitourinary tract infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Gingival abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Giardiasis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Gingivitis			

subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	10		
Groin infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
H1N1 influenza			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Helicobacter gastritis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Helicobacter infection			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Helminthic infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hepatitis B			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hepatic echinococcosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hepatitis C			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Herpes dermatitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Herpes ophthalmic			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Herpes simplex			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Herpes virus infection			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	15		
Herpes zoster disseminated			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Herpes zoster infection neurological			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Herpes zoster oticus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hordeolum			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Impetigo			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Implant site infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Incision site infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Infected bite			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Infected fistula			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Infected skin ulcer			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Infection			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Infection parasitic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	49 / 2040 (2.40%)		
occurrences (all)	51		
Injection site infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Kidney infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Joint abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Labyrinthitis			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Laryngitis			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Laryngitis bacterial			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Laryngitis viral			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Latent syphilis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Lip infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Liver abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Localised infection			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Lower respiratory tract infection			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	16		
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lyme disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lymphadenitis bacterial			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lymphangitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Molluscum contagiosum			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mycobacterium abscessus infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nail bed infection bacterial			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	41 / 2040 (2.01%)		
occurrences (all)	51		

Nail infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oesophageal candidiasis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Onychomycosis			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	10		
Oophoritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Oral bacterial infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oral fungal infection			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Oral herpes			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Oral infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oral viral infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Osteomyelitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Otitis externa			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Otitis externa bacterial			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Otitis media			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Otitis media acute			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Otitis media chronic			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Otitis media bacterial			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Parasitic gastroenteritis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Paronychia			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Parotitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Periodontitis			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	11		
Peritonitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		



Peritonsillar abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	29 / 2040 (1.42%)		
occurrences (all)	30		
Pharyngitis bacterial			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Pharyngotonsillitis			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Pneumonia			
subjects affected / exposed	19 / 2040 (0.93%)		
occurrences (all)	22		
Pneumococcal infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pneumonia adenoviral			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pneumonia bacterial			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Pneumonia escherichia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pneumonia viral			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Post procedural infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary tuberculosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Postoperative wound infection subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Pulpitis dental subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 3		
Pyelitis subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Pyelocystitis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Pyelonephritis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Pyelonephritis chronic subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Pyometra subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Rash pustular subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Respiratory tract infection subjects affected / exposed occurrences (all)	20 / 2040 (0.98%) 22		
Respiratory tract infection viral subjects affected / exposed occurrences (all)	6 / 2040 (0.29%) 6		
Respiratory tract infection bacterial subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Rhinitis subjects affected / exposed occurrences (all)	14 / 2040 (0.69%) 17		

Root canal infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Sepsis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Septic encephalopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Septic shock			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sialoadenitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sinobronchitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	11		
Sinusitis bacterial			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Skin bacterial infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin candida			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Soft tissue infection			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Skin infection			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		

Staphylococcal infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Subcutaneous abscess			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tick-borne fever			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tinea capitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tinea infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tinea pedis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Tonsillitis			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Tonsillitis bacterial			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tooth abscess			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Tooth infection			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Tracheitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tracheobronchitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		

Tuberculosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Upper respiratory fungal infection			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	130 / 2040 (6.37%)		
occurrences (all)	187		
Upper respiratory tract infection bacterial			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Urethritis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urinary tract infection bacterial			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	9		
Urinary tract infection			
subjects affected / exposed	97 / 2040 (4.75%)		
occurrences (all)	108		
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urinary tract infection fungal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Urinary tract infection pseudomonal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vaginal abscess			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Vaginal infection				
subjects affected / exposed	2 / 2040 (0.10%)			
occurrences (all)	2			
Varicella zoster virus infection				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences (all)	0			
Viral diarrhoea				
subjects affected / exposed	4 / 2040 (0.20%)			
occurrences (all)	5			
Viral infection				
subjects affected / exposed	3 / 2040 (0.15%)			
occurrences (all)	3			
Viral rash				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences (all)	0			
Viral pharyngitis				
subjects affected / exposed	4 / 2040 (0.20%)			
occurrences (all)	4			
Viral rhinitis				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences (all)	1			
Viral skin infection				
subjects affected / exposed	1 / 2040 (0.05%)			
occurrences (all)	2			
Viral upper respiratory tract infection				
subjects affected / exposed	217 / 2040 (10.64%)			
occurrences (all)	268			
Vulval abscess				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences (all)	0			
Vulvitis				
subjects affected / exposed	0 / 2040 (0.00%)			
occurrences (all)	0			
Vulvovaginal candidiasis				
subjects affected / exposed	0 / 2040 (0.00%)			

occurrences (all)	0		
Vulvovaginal mycotic infection			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Vulvovaginitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Wound infection			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Wound infection bacterial			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Wound infection staphylococcal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vascular disorders			
Aneurysm			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Angiosclerosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Aortic aneurysm			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Aortic arteriosclerosis			
subjects affected / exposed	11 / 2040 (0.54%)		
occurrences (all)	11		
Aortic dilatation			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Aortic calcification			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Aortic elongation			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aortic disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Aortic stenosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Aortic thrombosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Arterial insufficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Arteriosclerosis			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Arterial stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Arterial occlusive disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Blood pressure fluctuation			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Blood pressure inadequately controlled			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Circulatory collapse			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		



Haematoma			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	17		
Essential hypertension			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Diastolic hypotension			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	113 / 2040 (5.54%)		
occurrences (all)	125		
Hot flush			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Hypertensive angiopathy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hypertensive crisis			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Hypertensive emergency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ischaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Intermittent claudication			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Labile hypertension			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Labile blood pressure			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lymphostasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Microangiopathy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lymphoedema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Orthostatic hypotension			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pallor			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pelvic venous thrombosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Peripheral artery aneurysm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral artery stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Peripheral artery thrombosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Peripheral coldness			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Peripheral ischaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Peripheral vascular disorder			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	6		
Peripheral venous disease			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	8		
Phlebitis			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Phlebitis deep			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Phlebitis superficial			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Poor peripheral circulation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Post thrombotic syndrome			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Raynaud's phenomenon			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Subgaleal haematoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Thrombophlebitis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Thrombophlebitis superficial			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		

Thrombosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Varicophlebitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Varicose ulceration			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Varicose vein			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		
Varicose vein ruptured			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vascular calcification			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vascular insufficiency			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vasculitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vasodilatation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vena cava thrombosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Venous thrombosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Venous thrombosis limb			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Surgical and medical procedures			
Blepharoplasty			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Dental care			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Female genital operation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Intervertebral disc operation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nerve block			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Oral surgery			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Skin neoplasm excision			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Spinal fusion surgery			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tooth extraction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Suture insertion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Adrenal neoplasm			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Adrenal adenoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Adenoma benign			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Basal cell carcinoma			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Angiomyolipoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Benign lung neoplasm			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Benign female reproductive tract neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Benign breast neoplasm			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Benign neoplasm of eyelid			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Benign neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Benign neoplasm of adrenal gland			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Benign neoplasm of skin			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		

Benign neoplasm of thyroid gland			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Bowen's disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast cancer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Benign renal neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast fibroma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Chronic myeloid leukaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Colon neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Colon adenoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Essential thrombocythaemia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Eye naevus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Fibroadenoma of breast			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Fibrous histiocytoma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Fibroma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Haemangioma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Haemangioma of bone			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Haemangioma of liver			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Hepatic neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypergammaglobulinaemia benign monoclonal			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Invasive breast carcinoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Infected neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lipoma			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Lung neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		



Lung neoplasm malignant subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Malignant melanoma subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Lymphoma subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Melanocytic naevus subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Malignant neoplasm of eyelid subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Meningioma subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Monoclonal gammopathy subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Myelodysplastic syndrome subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Neoplasm malignant subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Non-Hodgkin's lymphoma unspecified histology indolent stage I subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Oesophageal adenocarcinoma stage 0 subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Osteoma subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Osteochondroma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Primary myelofibrosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pyogenic granuloma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rectal adenoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Renal neoplasm			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retroperitoneal cancer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Seborrhoeic keratosis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Skin papilloma			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Squamous cell carcinoma			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sweat gland tumour			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Thyroid cancer			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Uterine leiomyoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vulval cancer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Allergy to animal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Allergy to arthropod sting			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Allergy to arthropod bite			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Allergy to chemicals			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Drug hypersensitivity			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Food allergy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypersensitivity			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	4		
Iodine allergy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mite allergy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Oral allergy syndrome			

subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Seasonal allergy subjects affected / exposed occurrences (all)	4 / 2040 (0.20%) 4		
Social circumstances			
Diet noncompliance subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Immobile subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
General disorders and administration site conditions			
Administration site erythema subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 2		
Administration site haematoma subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Administration site pain subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Administration site pruritus subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Administration site reaction subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Administration site swelling subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Adverse drug reaction subjects affected / exposed occurrences (all)	2 / 2040 (0.10%) 2		
Asthenia subjects affected / exposed	49 / 2040 (2.40%)		

occurrences (all)	56		
Axillary pain			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Calcinosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Catheter site extravasation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Chest pain			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Chills			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	8		
Complication associated with device			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cyst			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Drug intolerance			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	5		
Discomfort			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	3		
Exercise tolerance decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Exercise tolerance increased			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Extravasation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Eye complication associated with device			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Face oedema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Facial pain			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	21 / 2040 (1.03%)		
occurrences (all)	21		
Feeling abnormal			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Feeling hot			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Foreign body reaction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
General physical health deterioration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gait disturbance			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Generalised oedema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hernia			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Impaired healing			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Impaired self-care			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	13 / 2040 (0.64%)		
occurrences (all)	13		
Injection site bruising			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Injection site erythema			
subjects affected / exposed	26 / 2040 (1.27%)		
occurrences (all)	53		
Injection site haematoma			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Injection site haemorrhage			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	13		
Injection site hypersensitivity			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Injection site inflammation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Injection site macule			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Injection site oedema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Injection site pain			

subjects affected / exposed	32 / 2040 (1.57%)		
occurrences (all)	70		
Injection site papule			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Injection site pruritus			
subjects affected / exposed	17 / 2040 (0.83%)		
occurrences (all)	26		
Injection site rash			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	12		
Injection site swelling			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	11		
Injection site urticaria			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	5		
Injection site vesicles			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Injection site warmth			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Injury associated with device			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Local swelling			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Localised oedema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Mass			



subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Medical device pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Medical device site joint pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mucosal atrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mucosal hyperaemia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nodule			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	18 / 2040 (0.88%)		
occurrences (all)	18		
Oedema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	34 / 2040 (1.67%)		
occurrences (all)	34		
Pain			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	12		
Peripheral swelling			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	12		
Polyp			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pseudocyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	20		
Sensation of foreign body			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Suprapubic pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Swelling			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Ulcer			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Ulcer haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vaccination site rash			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vessel puncture site erythema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vessel puncture site haematoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vessel puncture site swelling			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Xerosis			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Abnormal dreams			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Acute stress disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Adjustment disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Adjustment disorder with depressed mood			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Affective disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Agitation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	14 / 2040 (0.69%)		
occurrences (all)	14		
Anxiety disorder			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Anxiety disorder due to a general medical condition			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Apathy			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bipolar disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bruxism			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Compulsive hoarding			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Daydreaming			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	42 / 2040 (2.06%)		
occurrences (all)	45		
Depressed mood			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		
Delirium			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Depressive symptom			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Drug use disorder			

subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Emotional distress			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Feelings of worthlessness			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Frustration tolerance decreased			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Generalised anxiety disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Grief reaction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hallucination, visual			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Hallucinations, mixed			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	34 / 2040 (1.67%)		
occurrences (all)	35		
Initial insomnia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Irritability			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Major depression			

subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mania			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mental disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Mental status changes			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Middle insomnia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Mood altered			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Mood disorder due to a general medical condition			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nervousness			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nightmare			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Panic attack			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		
Panic disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Persistent depressive disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		

Pica			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Schizophrenia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Senile psychosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Somatic symptom disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Stress			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Tension			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Adnexa uteri cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Atrophic vulvovaginitis			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Breast calcifications			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast discharge			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Breast disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Breast enlargement			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast inflammation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast haematoma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Breast mass			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Breast pain			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Cervical dysplasia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cervical polyp			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cervix inflammation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Endometrial disorder			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cystocele			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Endometrial hyperplasia			
subjects affected / exposed	0 / 2040 (0.00%)		



occurrences (all)	0		
Endometrial hypertrophy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Endometriosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Fallopian tube cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Genital discharge			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Genital haemorrhage			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Genital pain			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Genital prolapse			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Genital tract inflammation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Genital ulceration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Menopausal symptoms			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Metrorrhagia			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Nipple disorder			
subjects affected / exposed	0 / 2040 (0.00%)		

occurrences (all)	0		
Ovarian cyst			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pelvic cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pelvic pain			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Perineal pain			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Rectocele			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Retracted nipple			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Uterine cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Uterine haemorrhage			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Uterine polyp			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Uterine prolapse			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Vaginal discharge			
subjects affected / exposed	1 / 2040 (0.05%)		

occurrences (all)	1		
Vaginal dysplasia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vaginal disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Vaginal prolapse			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vaginal ulceration			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vulva cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vulvovaginal burning sensation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Vulvovaginal dryness			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vulvovaginal pruritus			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Allergic bronchitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Allergic cough			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Allergic respiratory disease			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	12		
Allergic respiratory symptom			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Atelectasis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Asthmatic crisis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bronchial obstruction			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bronchial hyperreactivity			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Bronchiectasis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Bronchitis chronic			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Bronchospasm			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Catarrh			
subjects affected / exposed	5 / 2040 (0.25%)		
occurrences (all)	5		

Choking			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	21 / 2040 (1.03%)		
occurrences (all)	25		
Chronic respiratory failure			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	74 / 2040 (3.63%)		
occurrences (all)	81		
Dry throat			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Dysphonia			
subjects affected / exposed	6 / 2040 (0.29%)		
occurrences (all)	6		
Dyspnoea			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	15		
Dyspnoea exertional			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Epistaxis			
subjects affected / exposed	8 / 2040 (0.39%)		
occurrences (all)	11		
Emphysema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Haemoptysis			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Hiccups			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	2		

Hydrothorax			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypoventilation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Increased upper airway secretion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Laryngeal oedema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Interstitial lung disease			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Laryngitis allergic			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Lung disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Lung hyperinflation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Nasal discomfort			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Nasal dryness			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nasal inflammation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Nasal mucosal hypertrophy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nasal polyps			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nasal pruritus			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Nasal septum deviation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Obstructive airways disorder			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	3		
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	9 / 2040 (0.44%)		
occurrences (all)	9		
Pharyngeal inflammation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pharyngeal ulceration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Pleural adhesion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pleural calcification			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pleural thickening			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pleurisy			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pneumonia aspiration			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	10 / 2040 (0.49%)		
occurrences (all)	10		
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary calcification			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary congestion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		



Pulmonary fibrosis			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Pulmonary granuloma			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary hypertension			
subjects affected / exposed	7 / 2040 (0.34%)		
occurrences (all)	7		
Pulmonary infarction			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary mass			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Pulmonary oedema			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Rales			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Pulmonary vascular disorder			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Respiratory disorder			
subjects affected / exposed	3 / 2040 (0.15%)		
occurrences (all)	4		
Respiratory alkalosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Respiratory distress			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Respiratory tract congestion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Rhinorrhoea			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	4 / 2040 (0.20%)		
occurrences (all)	4		
Sinus congestion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Sputum increased			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Tonsillar cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Upper respiratory tract congestion			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Vocal cord cyst			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Biliary colic			
subjects affected / exposed	2 / 2040 (0.10%)		
occurrences (all)	2		
Bile duct stone			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Biliary dilatation			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cholangitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cholecystitis			
subjects affected / exposed	1 / 2040 (0.05%)		
occurrences (all)	1		
Cholecystitis acute			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cholecystitis chronic			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Cholelithiasis			
subjects affected / exposed	12 / 2040 (0.59%)		
occurrences (all)	12		
Drug-induced liver injury			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		
Gallbladder polyp			
subjects affected / exposed	0 / 2040 (0.00%)		
occurrences (all)	0		

Granulomatous liver disease subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hepatic atrophy subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Hepatic cirrhosis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hepatic cyst subjects affected / exposed occurrences (all)	9 / 2040 (0.44%) 9		
Hepatic function abnormal subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Hepatic steatosis subjects affected / exposed occurrences (all)	3 / 2040 (0.15%) 3		
Hepatic lesion subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hepatitis subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Hepatobiliary disease subjects affected / exposed occurrences (all)	1 / 2040 (0.05%) 1		
Hypertransaminasaemia subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Jaundice subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
Liver disorder subjects affected / exposed occurrences (all)	3 / 2040 (0.15%) 3		

Liver injury subjects affected / exposed occurrences (all)	0 / 2040 (0.00%) 0		
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## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 April 2012	<ul style="list-style-type: none"><li>- Subjects with a reported history of hearing loss associated with cranial nerve VIII compression due to excessive bone growth were excluded from study participation.</li><li>- A physician was to be available during administration of investigational product, and all subjects were closely observed for approximately 30 minutes after dosing with IP.</li><li>- The investigator was to be alerted if a subject experienced a BMD loss from baseline of <math>\geq 7\%</math> at the total hip and/or at the lumbar spine at any time during the study, and was required to discuss implications for individual fracture risk, alternative treatment options, and options for continuing in the study with the subject.</li></ul>
14 November 2012	<p>Following regulatory agency feedback, this amendment incorporated changes to facilitate optimal evaluation of the risk/benefit profile of romosozumab, to clarify statistical considerations, and to outline expectation for reporting of serious adverse events. Study procedures were simplified there was no impact on the evaluation of study objectives.</p> <ul style="list-style-type: none"><li>- Amended exclusion criteria to ensure that pre-existing disorders and/or the administration of medications did not confound the risk/benefit assessment for romosozumab.</li><li>- Amended proscribed treatments during the study to ensure those did not confound the risk/benefit assessment for romosozumab.</li><li>- Provided more detail on the adjudication of possible events of osteonecrosis of the jaw, atypical femoral fractures, and cardiovascular events.</li></ul> <p>Statistical considerations:</p> <ul style="list-style-type: none"><li>- Clarified that worsening vertebral fractures were considered for endpoints evaluating the incidence of all fractures.</li><li>- For endpoints evaluating the incidence of major osteoporotic fractures, corrected the definition to include forearm instead of wrist fractures.</li><li>- Baseline total hip BMD T-score was aligned with the Statistical Analysis Plan as an adjustment factor for the evaluation of new vertebral fracture incidence.</li></ul> <p>Serious adverse event reporting:</p> <ul style="list-style-type: none"><li>- Specified that serious adverse events must be reported within 24 hours after the investigator's knowledge of the event and clarified the point of reference for evaluation of expectedness of serious adverse events.</li></ul> <p>Changes to study procedures:</p> <ul style="list-style-type: none"><li>- Clarified the day 1 lumbar spine DXA scan may have been taken together with the screening proximal femur DXA scan for subject convenience.</li><li>- Replaced the month 21 clinic visit with a telephone call.</li><li>- For subjects participating in the Imaging and PK/BTM /Biomarker Substudy, the spine QCT assessments at month 36 and the end-of-study visits were eliminated.</li></ul>
21 June 2013	<p>The eligibility criteria were modified to allow participation of a wider range of subjects. Criteria revisions included the following:</p> <ul style="list-style-type: none"><li>- Lowering the minimum age from 60 to 55 years and allowing 3 additional qualifying BMD and fracture history combinations.</li><li>- The protocol-mandated off-treatment times for exclusionary medications were revised.</li><li>- Rescreening was allowed for subjects who previously failed screening if in the opinion of the investigator the reason for the initial screen failure has resolved or was no longer applicable.</li><li>- Based on regulatory agency feedback, assessments for formation of antiromosozumab antibodies were added at the month 1 and month 3 study visits to allow a more comprehensive characterization of the antibody response.</li><li>- Retesting of serum calcium would be permitted within the screening window if the initial test indicated an elevated level of serum calcium within 1.1 x the upper limit of normal.</li></ul>

08 July 2015	<p>The protocol was amended to include the addition of a Final Analysis. The study's previous primary analysis remained unchanged.</p> <ul style="list-style-type: none"> <li>- Upon completion of the primary analysis period, subjects were followed for nonvertebral fractures. Subjects and site personnel remained blinded to initial treatment assignments and the study proceeded in an event-driven manner. The final analysis (end-of-study) occurred when nonvertebral fracture events were confirmed for at least 440 subjects, or earlier if the primary analysis demonstrated superiority of romosozumab treatment for nonvertebral fracture risk reduction. The duration of participation for subjects was changed from 25 to 59 months if study completion was achieved at primary analysis, or from 37 to 71 months if study completion was achieved when 440 subjects experienced a nonvertebral fracture.</li> <li>- Approximately 200 subjects were planned to be enrolled in an Imaging and PK/BTM/Biomarker Substudy, with a subset of approximately 100 subjects participating in the imaging (DXA, QCT) portion of the substudy.</li> <li>- The exclusion criteria for hyper-/hypothyroidism and hyper-/hypoparathyroidism were clarified.</li> <li>- The month 15 study visit was eliminated for all but the substudy participants, and sampling for antibody testing was added to the month 18 visit. The end of primary analysis and end-of-study visits were replaced by telephone contact.</li> </ul>
14 September 2016	<ul style="list-style-type: none"> <li>- Moved the following month-12 exploratory endpoints to secondary endpoints: nonvertebral fracture, hip fracture, major osteoporotic fracture (hip, forearm, humerus, and clinical vertebral).</li> <li>- Added clinical vertebral fracture as a new month-12 secondary endpoint.</li> <li>- Added new endpoints to the overall study period and the month 12 to 24 open-label alendronate period.</li> <li>- Added the following new secondary endpoints through month 24 during the primary analysis period: clinical fracture, nonvertebral fracture, hip fracture, and clinical vertebral fracture.</li> <li>- Based on regulatory agency feedback, DXA BMD endpoints were added to the testing sequence for multiplicity adjustment.</li> </ul>

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported