Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Study to Determine the Treatment Effect of Denosumab in Subjects With Non-Metastatic Breast Cancer Receiving Aromatase Inhibitor Therapy

Summary

EudraCT number	2005-005275-15
Trial protocol	AT SE
Global end of trial date	09 August 2020

Results information

Result version number	v1 (current)
This version publication date	04 August 2023
First version publication date	04 August 2023

Trial information

Trial identification

Sponsor protocol code	20050209

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00556374
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Amgen Inc.
Sponsor organisation address	One Amgen Center Drive, Thousand Oaks, CA, United States,
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
Date of interim/final analysis	09 August 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 August 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to determine whether denosumab compared to placebo reduced the rate of first (on study) clinical fracture (ie, clinically evident fracture with associated symptoms) in women with non-metastatic breast cancer receiving non-steroidal aromatase inhibitor therapy (AIT).

Protection of trial subjects:

This study was conducted in accordance with International Council for Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 December 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	66 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 3297
Country: Number of subjects enrolled	Sweden: 123
Worldwide total number of subjects	3420
EEA total number of subjects	3420

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)	1734
From 65 to 84 years	1669

85 years and over	17

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at 58 centers in Austria and Sweden from December 2006 to August 2020.

Data collected during the exploratory ZA substudy were not used for the final analysis of the main study.

Pre-assignment

Screening details:

Participants were randomized in a 1:1 ratio to receive either denosumab or placebo in the double-blind phase. Randomization was stratified by type of hospital, prior aromatase inhibitor usage and total lumbar spine BMD at baseline. Eligible participants continued into the open-label phase and receive denosumab for a maximum of 7 doses.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants randomized to receive the matching placebo subcutaneously (SC) once every 6 months (Q6M) in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.

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

Dosage and administration details:

60 mg SC Q6M in the open-label phase

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

Dosage and administration details:

Matching placebo administered SC Q6M

Arm title	Denosumab

Arm description:

Participants randomized to receive 60 mg denosumab SC once Q6M in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.

Arm type	Experimental

Investigational medicinal product name	Denosumab
Investigational medicinal product code	
Other name	Prolia®
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

60 mg SC Q6M

Number of subjects in period 1	Placebo	Denosumab
Started	1709	1711
Received Treatment in Double-blind Phase	1699	1700
Received Treatment in Open-label Phase	252 [1]	2 [2]
Completed	1242	1362
Not completed	467	349
Adverse event, serious fatal	158	127
Consent withdrawn by subject	235	205
Ongoing on Zoledronic Acid Substudy	50	-
Lost to follow-up	24	17

Notes:

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

Justification: Number of participants who completed includes both participants who completed either the double-blind phase or open-label phase.

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

Justification: Number of participants who completed includes both participants who completed either the double-blind phase or open-label phase.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants randomized to receive the matching placebo subcutaneously (SC) once every 6 months (Q6M) in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.	
Reporting group title	Denosumab
Reporting group description:	
Participants randomized to receive 60 mg denosumab SC once Q6M in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.	

Reporting group values	Placebo	Denosumab	Total
Number of subjects	1709	1711	3420
Age Categorical Units: Subjects			
< 50 years	31	34	65
50 - 59 years	448	473	921
60 - 69 years	755	782	1537
70 - 79 years	414	372	786
≥ 80 years	61	50	111
Age Continuous Units: years			
arithmetic mean	64.6	64.0	
standard deviation	± 8.0	± 7.9	-
Gender Categorical Units: Subjects			
Female	1709	1711	3420
Male	0	0	0
Race Units: Subjects			
White/Caucasian	1700	1702	3402
Asian	7	5	12
Hispanic/Latino	1	3	4
Black/Afro-Caribbean	0	1	1
Missing	1	0	1
Type of Hospital (Strata per Randomization) Units: Subjects			
Major Academic Center	632	633	1265
Other Center	1077	1078	2155
Prior Aromatase Inhibitor Use (Strata per Randomization) Units: Subjects			
No.	269	270	539
Yes.	1440	1441	2881
Total Lumbar Spine Bone Mineral Density T-score (Strata per Randomization)			
T-scores are standardized scores that reflect the standard deviations (SDs) above/below the normal			

mean for young adults. T-score ≥ -1.0: BMD is considered normal. T-score < -1.0: Low BMD.			
Units: Subjects			
< -1.0	775	773	1548
≥ -1.0	934	938	1872

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants randomized to receive the matching placebo subcutaneously (SC) once every 6 months (Q6M) in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.	
Reporting group title	Denosumab
Reporting group description:	
Participants randomized to receive 60 mg denosumab SC once Q6M in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.	

Primary: Time to First Clinical Fracture

End point title	Time to First Clinical Fracture
End point description:	
The time to first on-study clinical fracture was defined as the number of days from randomization to the date of the x-ray confirming the clinical fracture. A clinical fracture was any clinically evident fracture with associated symptoms and confirmed by x-ray. Participants who died or withdrew without experiencing a clinical fracture were censored at the date of last contact or study termination whichever was earlier. 99999: No data reported as not reached due to the low number of events.	
End point type	Primary
End point timeframe:	
From randomization until the primary analysis cut-off date of 26 March 2014; maximum time on main study at the cut-off was 87 months	

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1709	1711		
Units: Days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo vs Denosumab
Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	3420
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	< 0.0001 [2]
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.504

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.39
upper limit	0.65

Notes:

[1] - A hazard ratio < 1.0 indicates a lower average event rate and a longer fracture free time for denosumab relative to placebo.
[2] - Stratification factors are hospital type, prior use of aromatase inhibitor, and baseline lumbar spine BMD. Model includes treatment group as the independent variable and stratified by randomization stratification factors.

Secondary: Percent Change from Baseline in Total Lumbar Spine Bone Mineral Density (BMD) at Month 36

End point title	Percent Change from Baseline in Total Lumbar Spine Bone Mineral Density (BMD) at Month 36

End point description:

BMD was assessed by dual x-ray absorptiometry.

End point type	Secondary

End point timeframe:

Baseline and Month 36

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	245[3]	230[4]		
Units: Percent change in BMD				
least squares mean (confidence interval 95%)	-2.75 (-3.44 to -2.07)	7.27 (6.56 to 7.98)		

Notes:

[3] - All participants with evaluable lumbar spine BMD values at Baseline and Month 36

[4] - All participants with evaluable lumbar spine BMD values at Baseline and Month 36

Statistical analyses

Statistical analysis title	Placebo vs Denosumab
Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	475
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [5]
Method	ANCOVA
Parameter estimate	Difference from Placebo
Point estimate	10.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.04
upper limit	11.01

Notes:

[5] - Model includes treatment group as the independent variable and adjusted for baseline value and the randomization stratification factors. The Hochberg procedure was used to control for multiplicity.

Secondary: Percent Change from Baseline in Total Hip BMD at Month 36

End point title	Percent Change from Baseline in Total Hip BMD at Month 36

End point description:

End point type	Secondary

End point timeframe:

Baseline and Month 36

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	237[6]	231[7]		
Units: Percent change in BMD				
least squares mean (confidence interval 95%)	-3.32 (-4.06 to -2.58)	4.60 (3.85 to 5.35)		

Notes:

[6] - All participants with total hip BMD evaluable values at Baseline and Month 36

[7] - All participants with total hip BMD evaluable values at Baseline and Month 36

Statistical analyses

Statistical analysis title	Placebo vs Denosumab
Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	468
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [8]
Method	ANCOVA
Parameter estimate	Difference from the Placebo
Point estimate	7.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.87
upper limit	8.97

Notes:

[8] - Model includes treatment group as the independent variable and adjusted for baseline value and the randomization stratification factors. The Hochberg procedure was used to control for multiplicity.

Secondary: Percent Change from Baseline in Femoral Neck BMD at Month 36

End point title	Percent Change from Baseline in Femoral Neck BMD at Month 36

End point description:

End point type	Secondary

End point timeframe:

Baseline and Month 36

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238[9]	231[10]		
Units: Percent change in BMD				
least squares mean (confidence interval 95%)	-3.10 (-3.72 to -2.48)	3.41 (2.78 to 4.04)		

Notes:

[9] - All participants with evaluable femoral neck BMD values at Baseline and Month 36

[10] - All participants with evaluable femoral neck BMD values at Baseline and Month 36

Statistical analyses

Statistical analysis title	Placebo vs Denosumab
Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	469
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [11]
Method	ANCOVA
Parameter estimate	Difference from Placebo
Point estimate	6.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.62
upper limit	7.39

Notes:

[11] - Model includes treatment group as the independent variable and adjusted for baseline value and the randomization stratification factors. The Hochberg procedure was used to control for multiplicity.

Secondary: Bone Metastases-free Survival (BMFS)

End point title	Bone Metastases-free Survival (BMFS)

End point description:

BMFS was defined as the time interval from randomization to first occurrence of bone metastasis or death from any cause, whichever comes first. Participants last known to be alive, who did not experience bone metastasis, were censored at their last assessment (i.e., bone scan) date or at the last contact date, whichever comes first.

99999 = Not reached due to the low number of events.

End point type	Secondary

End point timeframe:

From randomization until end of main study, maximum time on main study was 152 months

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1709	1711		
Units: Days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo vs Denosumab

Statistical analysis description:

Analysis of BMFS was conditional on the outcome of DFS due to hierarchical testing strategy, therefore p-value not reported.

Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	3420
Analysis specification	Pre-specified
Analysis type	superiority[12]
Parameter estimate	Hazard ratio (HR)
Point estimate	0.808
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.654
upper limit	0.997

Notes:

[12] - A hazard ratio < 1.0 indicates a lower average event rate and a longer bone metastases-free time for denosumab relative to placebo.

Secondary: Number of Participants With New or Worsening Vertebral Fractures

End point title	Number of Participants With New or Worsening Vertebral Fractures

End point description:

Assessment of vertebral fractures was performed by an expert radiologist at the central imaging center using a semiquantitative grading scale: Grade 1, 20% to 25% reduction in vertebral height (anterior, middle, or posterior); Grade 2, 25% to 40% reduction in height; Grade 3, greater than 40% reduction in height.

A new vertebral fracture was defined as a fracture in a previously undeformed vertebrae including new compression fractures, defined as those compression fractures having a decrease in total anterior or posterior height of at least 25% from baseline. New vertebral fractures includes morphometric vertebral fractures identified from on study x-rays and clinical vertebral fractures confirmed by x-rays. Worsening of pre-existing fractures was defined as an increase in fracture severity of at least 1 grade on the semiquantitative scale.

End point type	Secondary

End point timeframe:

Month 36

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	809[13]	835[14]		
Units: Participants	55	31		

Notes:

[13] - All participants with Baseline and at least 1 post-baseline vertebral x-ray prior to or at Month 36

[14] - All participants with Baseline and at least 1 post-baseline vertebral x-ray prior to or at Month 36

Statistical analyses

Statistical analysis title	Placebo vs Debisumab
Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	1644
Analysis specification	Pre-specified
Analysis type	superiority[15]
P-value	= 0.007 [16]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	0.84

Notes:

[15] - Values < 1 for Odds Ratio favor denosumab.

[16] - Logistic regression model includes treatment groups as the independent variable and stratified by the randomization stratification factors.

Secondary: Number of Participants with New Vertebral Fractures

End point title	Number of Participants with New Vertebral Fractures

End point description:

Assessment of vertebral fractures was performed by an expert radiologist at the central imaging center using a semiquantitative grading scale: Grade 1, 20% to 25% reduction in vertebral height (anterior, middle, or posterior); Grade 2, 25% to 40% reduction in height; Grade 3, greater than 40% reduction in height.

A new vertebral fracture was defined as a fracture in a previously undeformed vertebrae including new compression fractures, defined as those compression fractures having a decrease in total anterior or posterior height of at least 25% from baseline. New vertebral fractures includes morphometric vertebral fractures identified from on study x-rays and clinical vertebral fractures confirmed by x-rays.

End point type	Secondary

End point timeframe:

Month 36

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	809[17]	835[18]		
Units: Participants	49	27		

Notes:

[17] - All participants with Baseline and at least 1 post-baseline vertebral x-ray prior to or at Month 36

[18] - All participants with Baseline and at least 1 post-baseline vertebral x-ray prior to or at Month 36

Statistical analyses

Statistical analysis title	Placebo vs Denosumab
Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	1644
Analysis specification	Pre-specified
Analysis type	superiority[19]
P-value	= 0.0088 [20]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.33
upper limit	0.85

Notes:

[19] - Values < 1 for Odds Ratio favor denosumab.

[20] - Logistic regression model includes treatment group as the independent variable and stratified by the randomization stratification factors.

Secondary: Disease-free Survival (DFS)

End point title	Disease-free Survival (DFS)

End point description:

Disease-free survival (DFS) was defined as the time interval from the randomization date to the date of first evidence of local or distant metastases, contra-lateral breast cancer, secondary carcinoma, or death from any cause (whichever occurred first). Participants last known to be alive, who did not experience recurrence of disease, were censored at their last contact date or at the data cut-off date whichever came first.

99999: Not reached due to low number of events.

End point type	Secondary

End point timeframe:

From randomization until the DFS data cut-off date of 15 September 2015; maximum time on main study at the cut-off was 102 months

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1709	1711		
Units: Days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo vs Denosumab

Statistical analysis description:

A hazard ratio < 1.0 indicates a lower average event rate and a longer disease free time for denosumab relative to placebo.

Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	3420
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0515 [21]
Method	Cox Proportional Hazards Model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.816
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1

Notes:

[21] - Model includes treatment group as the independent variable and stratified by the randomization stratification factors.

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS was defined as the time from randomization to death from any cause.

99999 = Not reached due to the low number of events.

End point type	Secondary

End point timeframe:

Randomization until end of main study, maximum duration of main study was 152 months

End point values	Placebo	Denosumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1709	1711		
Units: Days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

Statistical analysis title	Placebo vs Denosumab

Statistical analysis description:

Analysis of OS was conditional on the outcome of DFS due to hierarchical testing strategy, therefore p-value not reported.

Comparison groups	Placebo v Denosumab
Number of subjects included in analysis	3420
Analysis specification	Pre-specified
Analysis type	superiority[22]
Parameter estimate	Hazard ratio (HR)
Point estimate	0.802
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.635
upper limit	1.013

Notes:

[22] - A hazard ratio < 1.0 indicates a lower average event rate and a longer overall survival time for denosumab relative to placebo.

Adverse events information

Timeframe for reporting adverse events:

Deaths: 1st dose to end of main study, max time: 152 months. AEs: 1st dose to 30 days after the last dose in DB and OL phases, respectively. Median treatment time: 35.4 months (placebo) and 35.5 months (denosumab) in DB phase; 37 months in OL phase

Adverse event reporting additional description:

All participants who were randomized and received at least 1 dose of treatment; participants were analyzed according to their actual treatment received. For Deaths, participants who did not receive OL treatment and died in the long-term follow-up phase are included in the DB columns. MedDRA 17.1 used for the DB phase and 24.0 used for the OL phase.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Double-blind (DB) Phase: Placebo

Reporting group description:

Participants received the matching placebo SC Q6M in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.

Reporting group title	Open-label (OL) Phase: Denosumab/Denosumab

Reporting group description:

Participants who received denosumab in the double-blind phase who continued into the open-label phase, where they received denosumab 60 mg SC Q6M for a maximum of 7 additional doses.

Reporting group title	Open Label (OL) Phase: Placebo/Denosumab

Reporting group description:

Participants who received the matching placebo in the double-blind phase who continued into the open-label phase, where they received denosumab 60 mg SC Q6M for a maximum of 7 additional doses.

Reporting group title	Double-blind (DB) Phase: Denosumab

Reporting group description:

Participants received denosumab SC Q6M in the double-blind phase. All participants continued to receive an approved non-steroidal aromatase inhibitor therapy.

Serious adverse events	Double-blind (DB) Phase: Placebo	Open-label (OL) Phase: Denosumab/Denosumab	Open Label (OL) Phase: Placebo/Denosumab
Total subjects affected by serious adverse events			
subjects affected / exposed	515 / 1690 (30.47%)	0 / 1 (0.00%)	40 / 245 (16.33%)
number of deaths (all causes)	153	0	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	5 / 1690 (0.30%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Adenocarcinoma of colon			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign breast neoplasm			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lymph node neoplasm			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign salivary gland neoplasm			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	3 / 245 (1.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast adenoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder papilloma			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer metastatic			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer recurrent			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage III			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon neoplasm			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contralateral breast cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of liver			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of breast			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal tract adenoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic neoplasm			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory myofibroblastic tumour			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal adenocarcinoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo maligna			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal proliferative breast lesion			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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 papilloma of breast			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip and/or oral cavity cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobular breast carcinoma in situ			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant pleural effusion			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma in situ			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinum neoplasm			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melanocytic naevus			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lymph nodes			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	5 / 1690 (0.30%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to pleura			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to skin			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian fibroma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral fibroma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian adenoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian epithelial cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroma			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parathyroid tumour benign			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenoma			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland adenoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid adenoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma urethra			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyosarcoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval cancer			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 1690 (0.36%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			

subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery occlusion			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian steal syndrome			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subclavian artery stenosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			

subjects affected / exposed	14 / 1690 (0.83%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery occlusion			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Raynaud's phenomenon			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral venous disease			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal arteritis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	10 / 1690 (0.59%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Knee arthroplasty			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastectomy			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular lens implant			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hysterosalpingo-oophorectomy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast reconstruction			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hysterectomy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prophylaxis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oophorectomy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fibrosis			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fat necrosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device dislocation			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	7 / 1690 (0.41%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device connection issue			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device complication			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Local swelling			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperplasia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoidosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast disorder			
subjects affected / exposed	6 / 1690 (0.36%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adnexa uteri mass			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast calcifications			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cyst			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast discharge			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adnexa uteri cyst			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast enlargement			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast fibrosis			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast haematoma			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast necrosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast pain			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibrocystic breast disease			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical polyp			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspareunia			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial hyperplasia			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical dysplasia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrometra			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterovaginal prolapse			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine adhesions			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cheyne-Stokes respiration			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic paralysis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polyps			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal cyst			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary alveolar haemorrhage			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	11 / 1690 (0.65%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus polyp			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord polyp			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	5 / 1690 (0.30%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	8 / 1690 (0.47%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burnout syndrome			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed mood			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic attack			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic stress disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychosomatic disease			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Weight decreased			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Smear cervix abnormal			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial pressure increased			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mammogram abnormal			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonoscopy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure abnormal			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	5 / 1690 (0.30%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursa injury			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone contusion			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anastomotic stenosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	24 / 1690 (1.42%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 24	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodilution			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	6 / 1690 (0.36%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural bile leak			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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 inflammation			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative hernia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative thrombosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural intestinal perforation			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation alveolitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation pneumonitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation skin injury			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
subjects affected / exposed	5 / 1690 (0.30%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin abrasion			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haematoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suture rupture			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column injury			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic arthrosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular bypass dysfunction			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Gene mutation			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental hip dysplasia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve stenosis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute myocardial infarction			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial tachycardia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	11 / 1690 (0.65%)	0 / 1 (0.00%)	3 / 245 (1.22%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	5 / 1690 (0.30%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	11 / 1690 (0.65%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sick sinus syndrome			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acoustic neuritis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amnesia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amnestic disorder			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	9 / 1690 (0.53%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	13 / 1690 (0.77%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery disease			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar haemorrhage			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic coma			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial neuralgia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drop attacks			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Morton's neuralgia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meralgia paraesthetica			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medication overuse headache			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor neurone disease			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paresis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal nerve palsy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radicular syndrome			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Senile dementia			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal claudication			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small fibre neuropathy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIth nerve paralysis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agranulocytosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear canal stenosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniere's disease			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden hearing loss			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinnitus			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	10 / 1690 (0.59%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open angle glaucoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal degeneration			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular degeneration			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exfoliation glaucoma			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic retinopathy			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract nuclear			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract cortical			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	28 / 1690 (1.66%)	0 / 1 (0.00%)	2 / 245 (0.82%)
occurrences causally related to treatment / all	0 / 39	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blepharochalasis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal tear			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous haemorrhage			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous opacities			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal discomfort			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal faeces			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dental caries			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric antral vascular ectasia			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal angiodysplasia			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	7 / 1690 (0.41%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal stenosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal polyp			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal necrosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Painful defaecation			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal motility disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swollen tongue			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary cirrhosis primary			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	9 / 1690 (0.53%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder polyp			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis allergic			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired epidermolysis bullosa			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug eruption			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema nodosum			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keloid scar			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen sclerosus			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panniculitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stasis dermatitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar pain			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin necrosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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 ureteric			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis haemorrhagic			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic nephropathy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incontinence			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertonic bladder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral disorder			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urge incontinence			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Basedow's disease			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	12 / 1690 (0.71%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Acquired claw toe			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Exostosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's contracture			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical spinal stenosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cyst			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	8 / 1690 (0.47%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint effusion			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	15 / 1690 (0.89%)	0 / 1 (0.00%)	5 / 245 (2.04%)
occurrences causally related to treatment / all	0 / 18	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	6 / 1690 (0.36%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot deformity			
subjects affected / exposed	12 / 1690 (0.71%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	59 / 1690 (3.49%)	0 / 1 (0.00%)	2 / 245 (0.82%)
occurrences causally related to treatment / all	0 / 77	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscal degeneration			

subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudarthrosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal pain			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondyloarthropathy			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylolisthesis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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 synovial cyst			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon disorder			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis stenosans			
subjects affected / exposed	4 / 1690 (0.24%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigger finger			
subjects affected / exposed	6 / 1690 (0.36%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral foraminal stenosis			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torticollis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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 infective			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Borrelia infection			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	10 / 1690 (0.59%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 13	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection bacterial			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter gastritis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	9 / 1690 (0.53%)	0 / 1 (0.00%)	3 / 245 (1.22%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint abscess			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site infection			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site abscess			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected seroma			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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 bacterial			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	7 / 1690 (0.41%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal abscess			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	2 / 1690 (0.12%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	3 / 1690 (0.18%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
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 neuronitis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	9 / 1690 (0.53%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	1 / 245 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insulin resistance			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 1690 (0.00%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	1 / 1690 (0.06%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Double-blind (DB) Phase: Denosumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	521 / 1709 (30.49%)		
number of deaths (all causes)	127		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	4 / 1709 (0.23%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Adenocarcinoma of colon			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign breast neoplasm			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Benign lymph node neoplasm			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign salivary gland neoplasm			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer			

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bowen's disease			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast adenoma			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bladder papilloma			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer metastatic			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cancer recurrent			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Breast cancer stage III			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colon adenoma			

subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cervix carcinoma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholangiocarcinoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic lymphocytic leukaemia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Colon cancer				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Colon neoplasm				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contralateral breast cancer				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Haemangioma of liver				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibroadenoma of breast				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal tract adenoma				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Endometrial adenocarcinoma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic neoplasm				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Inflammatory myofibroblastic tumour				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal adenocarcinoma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lentigo maligna				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraductal proliferative breast lesion				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Leiomyosarcoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraductal papilloma of breast				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lip and/or oral cavity cancer				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lobular breast carcinoma in situ				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant pleural effusion				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Lung neoplasm malignant				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma in situ				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Mediastinum neoplasm				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Melanocytic naevus				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningioma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to lymph nodes				

subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Metastases to bone				
subjects affected / exposed	5 / 1709 (0.29%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Metastases to liver				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Metastases to lung				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningioma benign				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to peritoneum				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to pleura				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to skin				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian fibroma				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral fibroma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian adenoma				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Ovarian epithelial cancer				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papillary thyroid cancer				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parathyroid tumour benign				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal cancer				

subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Rectal adenocarcinoma			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal adenoma			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pituitary tumour benign			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Salivary gland adenoma			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Schwannoma			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thyroid neoplasm			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid adenoma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thyroid cancer				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma urethra				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine leiomyoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine leiomyosarcoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulval cancer				

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	5 / 1709 (0.29%)		
occurrences causally related to treatment / all	1 / 6		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Circulatory collapse			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Femoral artery occlusion			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bleeding varicose vein			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arteriovenous fistula			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arterial stenosis			

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic dissection			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subclavian steal syndrome			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subclavian artery stenosis			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	10 / 1709 (0.59%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iliac artery occlusion			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intermittent claudication			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lymphoedema			

subjects affected / exposed	5 / 1709 (0.29%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Raynaud's phenomenon				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral venous disease				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Thrombosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Temporal arteritis				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vasculitis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicose vein				
subjects affected / exposed	12 / 1709 (0.70%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis limb				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Knee arthroplasty				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mastectomy				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intraocular lens implant				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hysterosalpingo-oophorectomy				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Breast reconstruction				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hysterectomy				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prophylaxis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oophorectomy				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Fibrosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fat necrosis				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Face oedema				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device dislocation				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Chest pain				

subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Cyst				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Device connection issue				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chest discomfort				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Medical device complication				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Local swelling				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incarcerated hernia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Impaired healing				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hyperplasia				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 1709 (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	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Multi-organ failure				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Granuloma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Allergy to arthropod sting				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic reaction				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sarcoidosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Drug hypersensitivity				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Adenomyosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast disorder				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Adnexa uteri mass				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast calcifications				

subjects affected / exposed	4 / 1709 (0.23%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Breast cyst			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast discharge			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adnexa uteri cyst			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Breast enlargement			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast fibrosis			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Breast haematoma			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast necrosis			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Breast pain			

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fibrocystic breast disease			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cervical polyp			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cystocele			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspareunia			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Endometrial hyperplasia			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Cervical dysplasia			
subjects affected / exposed	4 / 1709 (0.23%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Vaginal prolapse			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydrometra			

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterovaginal prolapse				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Postmenopausal haemorrhage				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Rectocele				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine adhesions				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine polyp				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Uterine prolapse				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	7 / 1709 (0.41%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asthma				

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atelectasis			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cheyne-Stokes respiration			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Cough			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic paralysis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Dyspnoea exertional			
subjects affected / exposed	4 / 1709 (0.23%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Organising pneumonia			

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperventilation				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasal polyps				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Emphysema				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oropharyngeal pain				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pharyngeal cyst				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pleurisy				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary alveolar haemorrhage				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	12 / 1709 (0.70%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Pulmonary fibrosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary hypertension				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary mass				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus polyp				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vocal cord polyp				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sleep apnoea syndrome				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Depression				
subjects affected / exposed	8 / 1709 (0.47%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burnout syndrome				

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Depressed mood			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol withdrawal syndrome			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Mental disorder			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Panic attack			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post-traumatic stress disorder			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychosomatic disease			

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Weight decreased			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Smear cervix abnormal			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary arterial pressure increased			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mammogram abnormal			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glycosylated haemoglobin increased			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colonoscopy			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure abnormal			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bursa injury			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brain contusion			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bone contusion			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Animal bite			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anastomotic stenosis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			

subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ligament rupture			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ligament sprain			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	23 / 1709 (1.35%)		
occurrences causally related to treatment / all	0 / 25		
deaths causally related to treatment / all	0 / 0		
Haemodilution			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extradural haematoma			

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	0 / 1709 (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	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural complication				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural haematoma				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Post procedural haemorrhage				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural inflammation				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post-traumatic neck syndrome				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Postoperative hernia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Postoperative thrombosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural intestinal perforation				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Procedural pain				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Radiation alveolitis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radiation pneumonitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radiation skin injury				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Scar				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Seroma				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Skin abrasion				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Splenic haematoma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suture rupture				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Spinal column injury			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Traumatic arthrosis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular bypass dysfunction			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Gene mutation			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Developmental hip dysplasia			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			

Arrhythmia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Aortic valve incompetence				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	5 / 1709 (0.29%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute left ventricular failure				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute coronary syndrome				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial tachycardia				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	14 / 1709 (0.82%)			
occurrences causally related to treatment / all	0 / 16			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	8 / 1709 (0.47%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 1			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			
subjects affected / exposed	10 / 1709 (0.59%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular extrasystoles				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus tachycardia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sick sinus syndrome				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress cardiomyopathy				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Acoustic neuritis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Amnesia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Amnestic disorder				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular disorder				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	6 / 1709 (0.35%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Cerebral ischaemia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carotid artery aneurysm				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carpal tunnel syndrome				
subjects affected / exposed	14 / 1709 (0.82%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Carotid artery stenosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carotid artery disease				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebellar haemorrhage				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic coma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dementia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic inflammatory demyelinating polyradiculoneuropathy				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cervicobrachial syndrome				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cervical radiculopathy				

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cervical myelopathy			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intercostal neuralgia			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Guillain-Barre syndrome			
subjects affected / exposed	0 / 1709 (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 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial paresis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Facial neuralgia			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Drop attacks				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Monoplegia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Morton's neuralgia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meralgia paraesthetica				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medication overuse headache				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lumbar radiculopathy				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intracranial aneurysm				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Motor neurone disease				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nerve compression				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorder				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neuralgia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Paresis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peroneal nerve palsy				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polyneuropathy				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Radicular syndrome				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sciatica				
subjects affected / exposed	7 / 1709 (0.41%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Senile dementia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transient global amnesia				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Speech disorder				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal claudication				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Syncope				

subjects affected / exposed	6 / 1709 (0.35%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Small fibre neuropathy				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
VIIth nerve paralysis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular encephalopathy				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Lymphadenopathy				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphadenitis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukopenia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				

subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Blood loss anaemia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Agranulocytosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Deafness unilateral				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Deafness				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Ear canal stenosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meniere's disease				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Sudden hearing loss				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tinnitus				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Vertigo				
subjects affected / exposed	9 / 1709 (0.53%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Vertigo positional				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Vestibular disorder				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Retinal detachment				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Open angle glaucoma				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Retinal degeneration				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Macular fibrosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Macular degeneration				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glaucoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exfoliation glaucoma				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic retinopathy				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cataract nuclear				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Cataract cortical				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cataract				

subjects affected / exposed	16 / 1709 (0.94%)		
occurrences causally related to treatment / all	0 / 23		
deaths causally related to treatment / all	0 / 0		
Blepharochalasis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retinal tear			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vitreous haemorrhage			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitreous opacities			
subjects affected / exposed	0 / 1709 (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	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal discomfort			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			

subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wall haematoma			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abnormal faeces			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Abdominal hernia			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic gastritis			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis ischaemic			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Colon dysplasia			

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Crohn's disease				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dental caries				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diaphragmatic hernia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Diverticular perforation				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastric antral vascular ectasia				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis erosive				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal motility disorder				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis haemorrhagic			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	7 / 1709 (0.41%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal perforation			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			

subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Large intestinal stenosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal polyp				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Haematochezia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal necrosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic pseudocyst				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritoneal necrosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal polyp				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Painful defaecation				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal motility disorder				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				

subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Mallory-Weiss syndrome				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Large intestine polyp				
subjects affected / exposed	8 / 1709 (0.47%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Subileus				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Swollen tongue				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct stone				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Biliary cirrhosis primary				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary colic				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	8 / 1709 (0.47%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis chronic				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	14 / 1709 (0.82%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Drug-induced liver injury				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder polyp				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic cirrhosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Dermatitis allergic				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Diabetic foot				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Angioedema				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acquired epidermolysis bullosa				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dermal cyst				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Drug eruption				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eczema				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erythema nodosum				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperkeratosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Keloid scar				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lichen sclerosus				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Panniculitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rash				

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stasis dermatitis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	3 / 1709 (0.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Scar pain			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin necrosis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus ureteric				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cystitis haemorrhagic				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic nephropathy				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal failure acute				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incontinence				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery stenosis				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal colic				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertonic bladder				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress urinary incontinence				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Urethral disorder				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urge incontinence				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary incontinence				
subjects affected / exposed	1 / 1709 (0.06%)			
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 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Goitre				

subjects affected / exposed	21 / 1709 (1.23%)			
occurrences causally related to treatment / all	0 / 22			
deaths causally related to treatment / all	0 / 0			
Hyperparathyroidism				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperthyroidism				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Acquired claw toe				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exostosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dupuytren's contracture				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chondropathy				
subjects affected / exposed	6 / 1709 (0.35%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Chondromalacia				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical spinal stenosis				

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bursitis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bone pain			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bone cyst			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	6 / 1709 (0.35%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	10 / 1709 (0.59%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Ligament disorder			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint instability			

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint effusion			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	14 / 1709 (0.82%)		
occurrences causally related to treatment / all	0 / 20		
deaths causally related to treatment / all	0 / 0		
Lumbar spinal stenosis			
subjects affected / exposed	8 / 1709 (0.47%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc degeneration			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemarthrosis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foot deformity			
subjects affected / exposed	13 / 1709 (0.76%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Fistula			
subjects affected / exposed	0 / 1709 (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 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	62 / 1709 (3.63%)		
occurrences causally related to treatment / all	1 / 78		
deaths causally related to treatment / all	0 / 0		
Osteochondrosis			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meniscal degeneration			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mobility decreased			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			

subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Polyarthritis				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Polymyalgia rheumatica				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal column stenosis				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Rheumatoid arthritis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Scoliosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pseudarthrosis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal pain				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Spinal stenosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Synovitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spondyloarthropathy				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spondylolisthesis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Synovial cyst				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal synovial cyst				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon disorder				

subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Tenosynovitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tenosynovitis stenosans				
subjects affected / exposed	9 / 1709 (0.53%)			
occurrences causally related to treatment / all	1 / 10			
deaths causally related to treatment / all	0 / 0			
Trigger finger				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vertebral foraminal stenosis				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Torticollis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bacterial infection				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis infective				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				

subjects affected / exposed	5 / 1709 (0.29%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess jaw				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic sinusitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholecystitis infective				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	6 / 1709 (0.35%)			
occurrences causally related to treatment / all	1 / 7			
deaths causally related to treatment / all	0 / 0			
Breast abscess				
subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Borrelia infection				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Campylobacter gastroenteritis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalitis				

subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	15 / 1709 (0.88%)		
occurrences causally related to treatment / all	0 / 23		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye infection bacterial			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Febrile infection			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	6 / 1709 (0.35%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma infection			

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Helicobacter gastritis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	9 / 1709 (0.53%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal candidiasis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis aseptic			

subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastitis			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Localised infection			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint abscess			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Implant site infection			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incision site abscess			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infected seroma			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			

subjects affected / exposed	2 / 1709 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia legionella				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	9 / 1709 (0.53%)			
occurrences causally related to treatment / all	0 / 13			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paronychia				
subjects affected / exposed	0 / 1709 (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 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ophthalmic herpes zoster				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritoneal abscess				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Salpingitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rhinitis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Psoas abscess				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				

subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subcutaneous abscess				
subjects affected / exposed	6 / 1709 (0.35%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	4 / 1709 (0.23%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Tooth abscess				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tracheobronchitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Viral infection				

subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vestibular neuronitis				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	7 / 1709 (0.41%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Type 2 diabetes mellitus				
subjects affected / exposed	3 / 1709 (0.18%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Obesity				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Insulin resistance				
subjects affected / exposed	0 / 1709 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	1 / 1709 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				

subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	2 / 1709 (0.12%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	1 / 1709 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 1709 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Double-blind (DB) Phase: Placebo	Open-label (OL) Phase: Denosumab/Denosumab	Open Label (OL) Phase: Placebo/Denosumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	838 / 1690 (49.59%)	0 / 1 (0.00%)	0 / 245 (0.00%)
Vascular disorders			
Hot flush			
subjects affected / exposed	234 / 1690 (13.85%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	260	0	0
Hypertension			
subjects affected / exposed	94 / 1690 (5.56%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	99	0	0
General disorders and administration			

site conditions			
Fatigue			
subjects affected / exposed	100 / 1690 (5.92%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	107	0	0
Skin and subcutaneous tissue disorders			
Scar pain			
subjects affected / exposed	86 / 1690 (5.09%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	92	0	0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	111 / 1690 (6.57%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	122	0	0
Back pain			
subjects affected / exposed	146 / 1690 (8.64%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	167	0	0
Arthralgia			
subjects affected / exposed	446 / 1690 (26.39%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	595	0	0
Spinal pain			
subjects affected / exposed	73 / 1690 (4.32%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	83	0	0
Pain in extremity			
subjects affected / exposed	85 / 1690 (5.03%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	95	0	0
Osteoarthritis			
subjects affected / exposed	61 / 1690 (3.61%)	0 / 1 (0.00%)	0 / 245 (0.00%)
occurrences (all)	76	0	0

Non-serious adverse events	Double-blind (DB) Phase: Denosumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	882 / 1709 (51.61%)		
Vascular disorders			
Hot flush			
subjects affected / exposed	270 / 1709 (15.80%)		
occurrences (all)	297		
Hypertension			

subjects affected / exposed	111 / 1709 (6.50%)		
occurrences (all)	116		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	109 / 1709 (6.38%)		
occurrences (all)	121		
Skin and subcutaneous tissue disorders			
Scar pain			
subjects affected / exposed	78 / 1709 (4.56%)		
occurrences (all)	82		
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	139 / 1709 (8.13%)		
occurrences (all)	151		
Back pain			
subjects affected / exposed	151 / 1709 (8.84%)		
occurrences (all)	163		
Arthralgia			
subjects affected / exposed	441 / 1709 (25.80%)		
occurrences (all)	627		
Spinal pain			
subjects affected / exposed	89 / 1709 (5.21%)		
occurrences (all)	99		
Pain in extremity			
subjects affected / exposed	107 / 1709 (6.26%)		
occurrences (all)	126		
Osteoarthritis			
subjects affected / exposed	89 / 1709 (5.21%)		
occurrences (all)	104		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 June 2006	* Allowed for the use, with approval by the DMC, of DXA scans or x-ray films available within a 60-day window (rather than 35-day window) from the date of randomization. * Added information to the Patient Information Sheet about the reversibility of increased BMD after discontinuation of denosumab.
06 April 2010	* Increased the sample size from 2800 participants to 3400 participants and increased the estimated overall study duration to 96 months, including an enrolment period of approximately 71 months. * Removed an interim analysis for futility due to the availability of data from phase 3 studies evaluating denosumab's effects on BMD and fracture rate. * Changed the incidence of new or new and worsening vertebral fracture at month 12 and month 24 and change of BMD from baseline to month 12 and month 24 to exploratory endpoints. Endpoints at month 36 remained as secondary endpoints. * Changed the disease outcome-related endpoints from exploratory endpoints to secondary endpoints. * Further extended the time window for DXA scans and xrays to within 120 days of randomization.
15 August 2012	* The definition of postmenopausal status for participants * 60 years of age was clarified to require FSH and estradiol levels to be in the postmenopausal range. * The amendment removed requirement for a pregnancy test for participants < 60 years of age who have had a hysterectomy. * The definition of termination date was updated to the PADCD and a 1-year or 5-year follow-up period was added. * The investigational product was switched from vials to pre-filled syringes.
25 January 2016	* Extension of the long-term follow-up to 66 months after PADCD, as disease-free survival (DFS) interim results did not indicate futility * Addition of an open-label phase (OLP) during which denosumab was administered to participants who previously received placebo during the double-blind phase of the study * Added study procedural information for placebo-treated participants who did not continue into the OLP and for participants who entered the open label phase. * Added exploratory objective to investigate the potential prognostic and predictive impact of the effects of denosumab in the body, an exploratory objective was added to investigate potential bone turnover biomarkers, hormone serum levels, tumor biomarkers, RANK/L pathway and body mass index using biological material (eg, blood and tumor samples), and their impact on treatment outcomes.
01 April 2019	* Added a ZA study extension to the protocol. Consenting participants still on open label denosumab were to be randomized to be treated with either a bisphosphonate or standard of care upon denosumab discontinuation * Added exploratory objective to evaluate the impact of a single intravenous (IV) ZA administration on BMD and fracture rates post-denosumab open-label discontinuation.
15 July 2019	* Reconfigured protocol so that the additional ZA administration study was structured and submitted as a substudy based on ethics committee recommendation. * Description of ZA substudy was removed from the body of the protocol to appendix.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Per protocol, only adverse events of special interest (oral events) and serious adverse events were collected in the open-label phase. Therefore, only these specific events are reported in the Adverse Events section for the open-label groups.

Notes: