



## Clinical trial results:

### An Observational Follow-Up Study for: A Phase III Randomized, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium (Protocol 018).

#### Summary

EudraCT number	2013-001526-26
Trial protocol	IT LT DE EE LV ES CZ PL BG DK HR
Global end of trial date	23 July 2016

#### Results information

Result version number	v1 (current)
This version publication date	19 May 2019
First version publication date	19 May 2019

#### Trial information

##### Trial identification

Sponsor protocol code	0822-083
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Merck Registration Number: MK-0822-083

Notes:

##### Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.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	23 July 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 July 2016
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The purpose of this observational follow-up study to MK-0822-018 was to collect follow-up safety information on participants who had discontinued from follow-up prior to reaching 5 years after randomization in study MK-0822-083.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 October 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 280
Country: Number of subjects enrolled	Belgium: 37
Country: Number of subjects enrolled	Brazil: 1611
Country: Number of subjects enrolled	Bulgaria: 220
Country: Number of subjects enrolled	Chile: 62
Country: Number of subjects enrolled	China: 610
Country: Number of subjects enrolled	Colombia: 1999
Country: Number of subjects enrolled	Croatia: 33
Country: Number of subjects enrolled	Czech Republic: 317
Country: Number of subjects enrolled	Denmark: 1048
Country: Number of subjects enrolled	Dominican Republic: 144
Country: Number of subjects enrolled	Estonia: 170
Country: Number of subjects enrolled	France: 42
Country: Number of subjects enrolled	Germany: 27
Country: Number of subjects enrolled	Guatemala: 293
Country: Number of subjects enrolled	Hong Kong: 211
Country: Number of subjects enrolled	Italy: 79
Country: Number of subjects enrolled	Japan: 454
Country: Number of subjects enrolled	Korea, Republic of: 194

Country: Number of subjects enrolled	Latvia: 53
Country: Number of subjects enrolled	Lithuania: 178
Country: Number of subjects enrolled	Mexico: 421
Country: Number of subjects enrolled	New Zealand: 86
Country: Number of subjects enrolled	Norway: 289
Country: Number of subjects enrolled	Peru: 603
Country: Number of subjects enrolled	Philippines: 116
Country: Number of subjects enrolled	Poland: 1171
Country: Number of subjects enrolled	Romania: 129
Country: Number of subjects enrolled	Russian Federation: 793
Country: Number of subjects enrolled	Serbia: 60
Country: Number of subjects enrolled	South Africa: 1129
Country: Number of subjects enrolled	Spain: 61
Country: Number of subjects enrolled	Switzerland: 27
Country: Number of subjects enrolled	Taiwan: 64
Country: Number of subjects enrolled	Ukraine: 84
Country: Number of subjects enrolled	United Kingdom: 1711
Country: Number of subjects enrolled	United States: 262
Country: Number of subjects enrolled	Australia: 3
Country: Number of subjects enrolled	India: 981
Country: Number of subjects enrolled	Lebanon: 19
Worldwide total number of subjects	16071
EEA total number of subjects	5565

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)	12
From 65 to 84 years	15650
85 years and over	409

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Of 16,071 participants who received blinded study treatment during the MK-0822-018 base study and first extension, 2887 participants participated in observational follow-up study MK-0822-083. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension.

### Period 1

Period 1 title	018 Base Study and First Extension
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Subject

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Odanacatib (ODN) 50 mg Once Weekly

Arm description:

Participants receive 50 mg of blinded odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also receive 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Arm type	Experimental
Investigational medicinal product name	Vitamin D3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5600 IU (2 x 2800 IU tablets) administered orally, once weekly, open label

Investigational medicinal product name	Odanacatib (ODN)
Investigational medicinal product code	MK-0822
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg tablet administered orally, once weekly

<b>Arm title</b>	Placebo Once Weekly
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Arm description:

Participants received blinded placebo to 50 mg of odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also received 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Arm type	Placebo
Investigational medicinal product name	Vitamin D3
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

5600 IU (2 x 2800 IU tablets) administered orally, once weekly, open label

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo tablet to match ODN 50 mg tablet, administered orally, once weekly

<b>Number of subjects in period 1</b>	Odanacatib (ODN) 50 mg Once Weekly	Placebo Once Weekly
Started	8043	8028
Completed	3640	2961
Not completed	4403	5067
Consent withdrawn by subject	1358	1254
Not Reported	46	67
Physician Decision	110	97
Adverse event, non-fatal	687	612
Completed Base Study, Did Not Enter 1st Extension	1795	2238
Final Disposition Unknown	-	1
Lost to follow-up	262	245
Protocol deviation	64	51
Lack of efficacy	81	502

## Period 2

Period 2 title	-083 Observational Follow-Up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

No study medication was provided as part of this observational follow-up study. However, during this study, sponsor personnel, the study investigator, and the participant remained blinded to the study drug treatment received in MK-0822-018 (Base study and the first Extension study).

## Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Formerly Received Odanacatib (ODN) 50 mg Once Weekly
Arm description: Participants received no intervention during this study. However, participants in this arm had received 50 mg of ODN once weekly as part of the MK-0822-018 study.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
<b>Arm title</b>	Formerly Received Placebo 50 mg Once Weekly (No intervention)
Arm description: Participants received no intervention during this study. However, participants in this arm had received placebo once weekly as part of the MK-0822-018 study.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2 <sup>[1]</sup>	Formerly Received Odanacatib (ODN) 50 mg Once Weekly	Formerly Received Placebo 50 mg Once Weekly (No intervention)
	Started	1181
Completed	1162	1673
Not completed	19	33
Consent withdrawn by subject	2	8
Adverse event, non-fatal	7	10
Other Protocol Specified Criteria	2	2
Unknown: Disposition Record Did Not Exist	2	2
Lost to follow-up	6	11

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all participants from the 018 period were required or expected to enter the 083 period. The 083 period is an observational follow-up study for participants who did not complete 5 years of treatment in 018.

## Baseline characteristics

### Reporting groups

Reporting group title	Odanacatib (ODN) 50 mg Once Weekly
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Reporting group description:

Participants receive 50 mg of blinded odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also receive 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Reporting group title	Placebo Once Weekly
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Reporting group description:

Participants received blinded placebo to 50 mg of odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also received 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Reporting group values	Odanacatib (ODN) 50 mg Once Weekly	Placebo Once Weekly	Total
Number of subjects	8043	8028	16071
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	6	12
From 65-84 years	7826	7824	15650
85 years and over	211	198	409
Age Continuous			
Units: years			
arithmetic mean	72.8	72.9	-
standard deviation	± 5.4	± 5.3	-
Gender Categorical			
Units: Subjects			
Female	8043	8028	16071
Male	0	0	0
Race			
Units: Subjects			
American Indian Or Alaska Native	97	88	185
Asian	1421	1411	2832
Black Or African American	129	132	261
Multi-Racial	1867	1839	3706
Native Hawaiian Or Other Pacific Islander	1	1	2
White	4528	4557	9085

## End points

### End points reporting groups

Reporting group title	Odanacatib (ODN) 50 mg Once Weekly
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Reporting group description:

Participants receive 50 mg of blinded odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also receive 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Reporting group title	Placebo Once Weekly
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Reporting group description:

Participants received blinded placebo to 50 mg of odanacatib weekly over the course of the base study and first extension study (5 years total). Participants also received 5600 IU Vitamin D3 and open-label supplemental calcium so that total daily calcium intake (from both dietary and supplemental sources) is approximately 1200 mg.

Reporting group title	Formerly Received Odanacatib (ODN) 50 mg Once Weekly
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Reporting group description:

Participants received no intervention during this study. However, participants in this arm had received 50 mg of ODN once weekly as part of the MK-0822-018 study.

Reporting group title	Formerly Received Placebo 50 mg Once Weekly (No intervention)
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Reporting group description:

Participants received no intervention during this study. However, participants in this arm had received placebo once weekly as part of the MK-0822-018 study.

Subject analysis set title	Participants Who Had Received Odanacatib During the 018 Study
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received oadanacatib 50 mg once weekly.

Subject analysis set title	Participants Who Had Received Placebo During the 018 Study
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received placebo once weekly.

### Primary: Number of Participants With Adverse Events (AEs) per 100 Patient-Years of Follow-up

End point title	Number of Participants With Adverse Events (AEs) per 100 Patient-Years of Follow-up
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End point description:

The number of participants experiencing  $\geq 1$  AE per 100 patient-years of follow-up was presented. An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received  $\geq 1$  dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.

End point type	Primary
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End point timeframe:

Up to approximately 90 months

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	92.11 (89.98 to 94.27)	91.42 (89.31 to 93.57)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.33
upper limit	3.7

### Primary: Number of Participants With Serious AEs per 100 Patient-Years of Follow-up

<b>End point title</b>	Number of Participants With Serious AEs per 100 Patient-Years of Follow-up
End point description:	
The number of participants with serious adverse events per 100 patient-years of follow-up was presented. An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received $\geq 1$ dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to approximately 90 months	

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	9.27 (8.91 to 9.64)	9.39 (9.03 to 9.76)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	0.4

### Primary: Number of Participants With AEs Leading to Death per 100 Patient-Years of Follow-up

End point title	Number of Participants With AEs Leading to Death per 100 Patient-Years of Follow-up
End point description:	
The number of participants with adverse events that led to death per 100 patient-years of follow-up was presented. An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received $\geq 1$ dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to approximately 90 months	

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	1.19 (1.07 to 1.31)	1.04 (0.93 to 1.16)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.01
upper limit	0.31

### Primary: Number of Participants With an Atypical Femoral Shaft Fracture Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With an Atypical Femoral Shaft Fracture Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description: The number of participants with an atypical femoral shaft fractures confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe: Up to 90 months	

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.03 (0.01 to 0.06)	0.00 (0.00 to 0.01)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	0.06

### Primary: Number of Participants With Cerebrovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Cerebrovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description:	
The number of participants with cerebrovascular events confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe:	
Up to approximately 90 months	

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.45 (0.38 to 0.53)	0.38 (0.31 to 0.45)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.02
upper limit	0.18

### Primary: Number of Participants With Cardiovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Cardiovascular Events Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description: The number of participants with cardiovascular events confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe: Up to approximately 90 months	

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.92 (0.82 to 1.03)	0.86 (0.76 to 0.97)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.08
upper limit	0.21

### Primary: Number of Participants With Skin Adverse Events (AEs) reported as an Event of Clinical Interest per 100 Patient-Years of Follow-up

End point title	Number of Participants With Skin Adverse Events (AEs) reported as an Event of Clinical Interest per 100 Patient-Years of Follow-up
End point description: The number of participants with skin AEs reported as events of clinical interest (ECI) per 100 patient-years of follow-up was presented. Protocol pre-specified skin AEs considered ECIs included all serious skin AEs, severe skin AEs, or skin AEs with skin thickening and hardening suggestive of morphea or systemic sclerosis (scleroderma). An AE was defined as any unfavorable and unintended sign, symptom, or disease (new or worsening) temporally associated with the use of study therapy, regardless of whether or not a causal relationship with the study therapy could be determined. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received $\geq 1$ dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary

End point timeframe:  
Up to approximately 90 months

<b>End point values</b>	Participants Who Had Received Olanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.15 (0.11 to 0.20)	0.15 (0.11 to 0.19)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Olanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.05
upper limit	0.07

### Primary: Number of Participants With Serious Respiratory Infections Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Serious Respiratory Infections Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description: The number of participants with serious respiratory infections confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received $\geq 1$ dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe: Up to approximately 90 months	

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.41 (0.34 to 0.48)	0.48 (0.41 to 0.56)		

### Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.03

### Primary: Number of Participants With Osteonecrosis of the Jaw Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Osteonecrosis of the Jaw Confirmed by Adjudication per 100 Patient-Years of Follow-up <sup>[1]</sup>
End point description: The number of participants with osteonecrosis of the jaw confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received ≥1 dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe: Up to approximately 90 months	

Notes:

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

Justification: Statistical analysis plan stipulated that if osteonecrosis of the jaw occurred in less than 4 participants in a treatment group, then only estimates within each treatment group would be presented. Therefore, per the plan, no statistical analysis is presented.

<b>End point values</b>	Participants Who Had Received Olanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8038		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.00 (0.00 to 0.01)	0.00 (0.00 to 0.01)		

### Statistical analyses

No statistical analyses for this end point

### Primary: Number of Participants With Morphea or Systemic Scleroses Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Morphea or Systemic Scleroses Confirmed by Adjudication per 100 Patient-Years of Follow-up
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End point description:

The number of participants with morphea or systemic sclerosis confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. All participants who received  $\geq 1$  dose of study treatment during the MK-0822-018 base study were included in the analysis, regardless of whether they later enrolled in MK-0822-083.

End point type	Primary
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End point timeframe:

Up to approximately 90 months

<b>End point values</b>	Participants Who Had Received Olanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.05 (0.03 to 0.08)	0.01 (0.00 to 0.03)		

## Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description: Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.01
upper limit	0.06

### Primary: Number of Participants With Delayed Fracture Unions Confirmed by Adjudication per 100 Patient-Years of Follow-up

End point title	Number of Participants With Delayed Fracture Unions Confirmed by Adjudication per 100 Patient-Years of Follow-up
End point description: The number of participants with delayed fracture unions confirmed by adjudication per 100 patient-years of follow-up was presented. Safety data from this follow-up study was pooled and analyzed with safety data from the MK-0822-018 base study and first extension. Participants who received $\geq 1$ dose of study treatment during the MK-0822-018 base study, and who had a fracture confirmed by adjudication during the MK-0822-018 base or first extension study, were included in the analysis, regardless of whether they later enrolled in MK-0822-083.	
End point type	Primary
End point timeframe: Up to approximately 90 months	

<b>End point values</b>	Participants Who Had Received Odanacatib During the 018 Study	Participants Who Had Received Placebo During the 018 Study		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8043	8028		
Units: Participants Per 100 Patient-Years				
number (confidence interval 95%)	0.73 (0.44 to 1.13)	0.56 (0.34 to 0.88)		

## Statistical analyses

<b>Statistical analysis title</b>	Difference in Rates
Statistical analysis description:	
Miettinen & Nurminen method based 95% confidence interval and rate difference	
Comparison groups	Participants Who Had Received Odanacatib During the 018 Study v Participants Who Had Received Placebo During the 018 Study
Number of subjects included in analysis	16071
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in rates
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.62

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to approximately 90 months

Adverse event reporting additional description:

AEs reported on follow-up arms of this study were pooled and analyzed with AEs from the respective treatment arms of the MK-0822-018 base study and first extension.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	18.0
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### Reporting groups

Reporting group title	Participants Who Had Received Placebo During the 018 Study
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Reporting group description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received placebo once weekly.

Reporting group title	Participants Who Had Received Olanacatib During the 018 Study
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Reporting group description:

This set represents data collected on participants during the MK-0822-018 base and first extension study, combined with data collected during the MK-0822-083 observational followup study, inclusive of participants who participated in MK-0822-018 but did not later enroll in MK-0822-083. During the MK-0822-018 study, these participants received oadanacatib 50 mg once weekly.

<b>Serious adverse events</b>	Participants Who Had Received Placebo During the 018 Study	Participants Who Had Received Olanacatib During the 018 Study	
Total subjects affected by serious adverse events			
subjects affected / exposed	2566 / 8028 (31.96%)	2528 / 8043 (31.43%)	
number of deaths (all causes)	341	388	
number of deaths resulting from adverse events	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	7 / 8028 (0.09%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 8	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 2	
Angiosarcoma metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Basal cell carcinoma		
subjects affected / exposed	76 / 8028 (0.95%)	83 / 8043 (1.03%)
occurrences causally related to treatment / all	0 / 92	0 / 98
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder cancer		
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma		
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain neoplasm		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer		
subjects affected / exposed	33 / 8028 (0.41%)	35 / 8043 (0.44%)
occurrences causally related to treatment / all	0 / 33	0 / 35
deaths causally related to treatment / all	0 / 1	0 / 0
Colon cancer		
subjects affected / exposed	17 / 8028 (0.21%)	24 / 8043 (0.30%)
occurrences causally related to treatment / all	0 / 17	0 / 24
deaths causally related to treatment / all	0 / 3	0 / 2
Colorectal cancer		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diffuse large B-cell lymphoma		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal carcinoma		

subjects affected / exposed	5 / 8028 (0.06%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	8 / 8028 (0.10%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Keratoacanthoma		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	4 / 8028 (0.05%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to lung		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to lymph nodes		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic squamous cell carcinoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuroendocrine tumour		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-Hodgkin's lymphoma		

subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Ovarian cancer		
subjects affected / exposed	4 / 8028 (0.05%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 4	1 / 8
deaths causally related to treatment / all	0 / 2	0 / 2
Ovarian epithelial cancer		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic carcinoma		
subjects affected / exposed	9 / 8028 (0.11%)	14 / 8043 (0.17%)
occurrences causally related to treatment / all	0 / 9	0 / 14
deaths causally related to treatment / all	0 / 6	0 / 8
Plasma cell myeloma		
subjects affected / exposed	6 / 8028 (0.07%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenoma		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland cancer		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	7 / 8028 (0.09%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma		

subjects affected / exposed	13 / 8028 (0.16%)	14 / 8043 (0.17%)
occurrences causally related to treatment / all	0 / 13	0 / 14
deaths causally related to treatment / all	0 / 1	0 / 1
Squamous cell carcinoma of skin		
subjects affected / exposed	11 / 8028 (0.14%)	18 / 8043 (0.22%)
occurrences causally related to treatment / all	0 / 11	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid neoplasm		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine cancer		
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Acute leukaemia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acute myeloid leukaemia		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Adenocarcinoma gastric		
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2
Adenocarcinoma of the cervix		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal cancer		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angiosarcoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Benign breast neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign lung neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign muscle neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of bladder		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Benign salivary gland neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign vulval neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct cancer		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Bladder neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bone cancer		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bone neoplasm		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Borderline mucinous tumour of ovary		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bowen's disease</b>		
subjects affected / exposed	6 / 8028 (0.07%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain cancer metastatic</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Breast cancer in situ</b>		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer metastatic</b>		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Breast cancer recurrent</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer stage III</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast neoplasm</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchial carcinoma</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchioloalveolar carcinoma</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carcinoid tumour of the stomach</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carcinoma in situ of skin</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebellar tumour</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebellopontine angle tumour</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix cancer metastatic</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Cervix carcinoma</b>		
subjects affected / exposed	3 / 8028 (0.04%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix carcinoma stage II</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Choroid melanoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Clear cell endometrial carcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer metastatic		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Colon neoplasm		
subjects affected / exposed	4 / 8028 (0.05%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Colorectal cancer recurrent		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ductal adenocarcinoma of pancreas		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysplastic naevus		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	0 / 8028 (0.00%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Essential thrombocythaemia		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fallopian tube cancer		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Female reproductive neoplasm		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Fibroadenoma of breast		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fibromatosis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Follicle centre lymphoma, follicular grade I, II, III stage II		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder adenocarcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gallbladder cancer		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	1 / 1	0 / 2
Gastric cancer		
subjects affected / exposed	6 / 8028 (0.07%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 2
Gastric cancer stage IV		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal neoplasm		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stromal tumour		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal tract adenoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gingival cancer		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glioblastoma		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Glioblastoma multiforme		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomus tumour		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemangioma</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemangioma of bone</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic cancer</b>		
subjects affected / exposed	4 / 8028 (0.05%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 4
<b>Hepatic neoplasm</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hepatocellular carcinoma</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
<b>Inflammatory carcinoma of the breast</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Intraductal papilloma of breast</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intraductal proliferative breast lesion</b>		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intraocular melanoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive breast carcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive lobular breast carcinoma		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Kaposi's sarcoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leiomyosarcoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo maligna		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Leukaemia		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Lip and/or oral cavity cancer			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lip squamous cell carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liposarcoma			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lobular breast carcinoma in situ			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	1 / 8028 (0.01%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 4	
Lung adenocarcinoma stage I			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma stage IV			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Lung cancer metastatic		
subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1
Lung carcinoma cell type unspecified stage IV		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lung neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	23 / 8028 (0.29%)	13 / 8043 (0.16%)
occurrences causally related to treatment / all	0 / 24	0 / 13
deaths causally related to treatment / all	0 / 5	0 / 6
Lymphangioma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoma		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Lymphoproliferative disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma in situ		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of ampulla of Vater		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of eyelid		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of renal pelvis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Malignant neoplasm of unknown primary site		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Malignant neoplasm progression		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant peritoneal neoplasm		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mantle cell lymphoma		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Medullary thyroid cancer		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melanocytic naevus		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melanoma recurrent		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mesothelioma		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Mesothelioma malignant		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metaplastic breast carcinoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to bone		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Metastases to central nervous system		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Metastases to peritoneum		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to pleura		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to skin		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastasis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic bronchial carcinoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic gastric cancer		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Metastatic neoplasm		

subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3
Metastatic salivary gland cancer		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic uterine cancer		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mucinous breast carcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mycosis fungoides		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome transformation		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myeloproliferative disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal cavity cancer		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Nasal neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasopharyngeal cancer		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neoplasm malignant		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Neuroendocrine carcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Neuroendocrine carcinoma metastatic		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer metastatic		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Non-small cell lung cancer stage IV		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal adenocarcinoma		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Oesophageal carcinoma		
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 3	2 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Oesophageal squamous cell carcinoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oligodendroglioma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oropharyngeal cancer		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Osteoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteosarcoma		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Ovarian adenoma		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer metastatic		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Ovarian epithelial cancer stage I		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma metastatic		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Pancreatic carcinoma stage IV		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic neoplasm		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Papillary serous endometrial carcinoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Papillary thyroid cancer		

subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Papilloma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parathyroid tumour benign		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic neoplasm		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal mesothelioma malignant		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal cancer		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Rectal cancer		

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectosigmoid cancer			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Refractory anaemia with an excess of blasts			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Refractory cytopenia with unilineage dysplasia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma stage II			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Renal oncocytoma</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retroperitoneal cancer</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sarcoma</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Schwannoma</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Seborrhoeic keratosis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Small cell lung cancer</b>		
subjects affected / exposed	1 / 8028 (0.01%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 4
<b>Small cell lung cancer limited stage</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Soft tissue neoplasm</b>		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord neoplasm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Splenic marginal zone lymphoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of lung		
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the cervix		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the oral cavity		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Superficial spreading melanoma stage unspecified		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

T-cell lymphoma			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Thymoma malignant			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid adenoma			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer metastatic			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsil cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell cancer of the renal pelvis and ureter			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ureteric cancer			

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral cancer			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	2 / 8028 (0.02%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine neoplasm			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulval cancer stage 0			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 5	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	10 / 8028 (0.12%)	17 / 8043 (0.21%)	
occurrences causally related to treatment / all	0 / 10	0 / 19	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypertension			

subjects affected / exposed	41 / 8028 (0.51%)	32 / 8043 (0.40%)
occurrences causally related to treatment / all	0 / 43	1 / 36
deaths causally related to treatment / all	0 / 1	0 / 0
Hypertensive emergency		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Varicose vein		
subjects affected / exposed	3 / 8028 (0.04%)	9 / 8043 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Venous thrombosis limb		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Accelerated hypertension		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic aneurysm		
subjects affected / exposed	4 / 8028 (0.05%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Aortic aneurysm rupture		

subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Aortic arteriosclerosis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic dissection		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Arterial disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arterial stenosis		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis		
subjects affected / exposed	2 / 8028 (0.02%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1
Bleeding varicose vein		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure fluctuation		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Circulatory collapse		
subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Distributive shock		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Essential hypertension		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Femoral artery occlusion		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	0 / 8028 (0.00%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hot flush		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		

subjects affected / exposed	20 / 8028 (0.25%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 21	0 / 12
deaths causally related to treatment / all	0 / 1	0 / 0
Hypotension		
subjects affected / exposed	3 / 8028 (0.04%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Hypovolaemic shock		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Iliac artery occlusion		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infarction		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	4 / 8028 (0.05%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		

subjects affected / exposed	5 / 8028 (0.06%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral circulatory failure		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Phlebitis		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Shock haemorrhagic		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Subgaleal haematoma		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporal arteritis			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	4 / 8028 (0.05%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose ulceration			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Adverse event			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	26 / 8028 (0.32%)	22 / 8043 (0.27%)
occurrences causally related to treatment / all	0 / 27	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	67 / 8028 (0.83%)	67 / 8043 (0.83%)
occurrences causally related to treatment / all	0 / 67	0 / 67
deaths causally related to treatment / all	0 / 67	0 / 67
Device battery issue		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device dislocation		
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	7 / 8028 (0.09%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Accidental death		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 2
Asthenia		
subjects affected / exposed	3 / 8028 (0.04%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 3
Capsular contracture associated with breast implant		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest discomfort		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cyst		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device adhesion issue		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device breakage		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device damage		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device malfunction		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Device material issue		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Drug intolerance		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Drug withdrawal syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Facial pain		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
General symptom		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hernia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ill-defined disorder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Impaired healing		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site reaction		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malaise		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device complication		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multi-organ disorder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Multi-organ failure		
subjects affected / exposed	6 / 8028 (0.07%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 6	0 / 9
Nodule		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		

subjects affected / exposed	0 / 8028 (0.00%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral administration complication			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	7 / 8028 (0.09%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue inflammation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strangulated hernia			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	2 / 8028 (0.02%)	15 / 8043 (0.19%)	
occurrences causally related to treatment / all	0 / 2	0 / 15	
deaths causally related to treatment / all	0 / 2	0 / 15	
Systemic inflammatory response syndrome			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Immune system disorders</b>			
<b>Anaphylactic reaction</b>			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anaphylactic shock</b>			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Drug hypersensitivity</b>			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypersensitivity</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sarcoidosis</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Social circumstances</b>			
<b>Immobile</b>			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Reproductive system and breast disorders</b>			
<b>Endometrial atrophy</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ovarian cyst			
subjects affected / exposed	6 / 8028 (0.07%)	12 / 8043 (0.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic floor muscle weakness			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	15 / 8028 (0.19%)	15 / 8043 (0.19%)	
occurrences causally related to treatment / all	0 / 16	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexa uteri mass			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adnexal torsion			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anisomastia			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical leukoplakia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical polyp		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colpocele		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cystocele		
subjects affected / exposed	2 / 8028 (0.02%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Dysfunctional uterine bleeding		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial hyperplasia		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Genital prolapse		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metrorrhagia		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic pain		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic prolapse		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectocele		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine polyp		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal fistula		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vaginal prolapse		
subjects affected / exposed	10 / 8028 (0.12%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval leukoplakia		

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vulvar dysplasia</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vulvovaginal pruritus</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>Asthma</b>			
subjects affected / exposed	19 / 8028 (0.24%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 24	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Chronic obstructive pulmonary disease</b>			
subjects affected / exposed	38 / 8028 (0.47%)	36 / 8043 (0.45%)	
occurrences causally related to treatment / all	0 / 49	0 / 47	
deaths causally related to treatment / all	0 / 4	0 / 5	
<b>Nasal polyps</b>			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pharyngeal cyst</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Pleural effusion</b>			
subjects affected / exposed	10 / 8028 (0.12%)	13 / 8043 (0.16%)	
occurrences causally related to treatment / all	0 / 10	0 / 14	
deaths causally related to treatment / all	0 / 2	0 / 2	
<b>Pulmonary embolism</b>			

subjects affected / exposed	28 / 8028 (0.35%)	31 / 8043 (0.39%)
occurrences causally related to treatment / all	0 / 31	0 / 32
deaths causally related to treatment / all	0 / 9	0 / 7
Pulmonary hypertension		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	7 / 8028 (0.09%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Respiratory distress		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Respiratory failure		
subjects affected / exposed	10 / 8028 (0.12%)	14 / 8043 (0.17%)
occurrences causally related to treatment / all	0 / 10	0 / 15
deaths causally related to treatment / all	0 / 6	0 / 8
Acute pulmonary oedema		
subjects affected / exposed	9 / 8028 (0.11%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 1
Acute respiratory distress syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Acute respiratory failure		

subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 3
Aspiration		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Asthmatic crisis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atelectasis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiectasis		
subjects affected / exposed	5 / 8028 (0.06%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Bronchitis chronic		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cough		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspnoea		

subjects affected / exposed	6 / 8028 (0.07%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eosinophilic pneumonia chronic		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottic cyst		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	2 / 8028 (0.02%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoxia		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Interstitial lung disease		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Laryngeal granuloma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal polyp		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung consolidation		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Mediastinal cyst		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Oesophagobronchial fistula</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pharyngeal pouch</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pickwickian syndrome</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pleurisy</b>		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pleuritic pain</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonia aspiration</b>		
subjects affected / exposed	5 / 8028 (0.06%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 3
<b>Pneumonitis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pneumothorax</b>		

subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 1
Pulmonary arteriopathy		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pulmonary fibrosis		
subjects affected / exposed	4 / 8028 (0.05%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 4
Pulmonary ossification		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary thrombosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory arrest		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Respiratory disorder		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract inflammation		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus polyp degeneration		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Throat irritation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal stenosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord disorder			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord polyp			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anxiety disorder due to a general medical condition		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar disorder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Confusional state		
subjects affected / exposed	3 / 8028 (0.04%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	10 / 8028 (0.12%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	1 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Dysthymic disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphemia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Major depression		

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Mental disorder</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Mood disorder due to a general medical condition</b>			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Panic attack</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychogenic pain disorder</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychotic disorder</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Suicide attempt</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Investigations</b>			
<b>Blood pressure increased</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Electrocardiogram QT prolonged</b>			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram abnormal			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Grip strength decreased			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Heart rate irregular			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	21 / 8028 (0.26%)	13 / 8043 (0.16%)	
occurrences causally related to treatment / all	0 / 25	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	8 / 8028 (0.10%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Contusion			

subjects affected / exposed	16 / 8028 (0.20%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 19	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
Femoral neck fracture		
subjects affected / exposed	66 / 8028 (0.82%)	36 / 8043 (0.45%)
occurrences causally related to treatment / all	0 / 70	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	42 / 8028 (0.52%)	46 / 8043 (0.57%)
occurrences causally related to treatment / all	0 / 43	1 / 51
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	12 / 8028 (0.15%)	11 / 8043 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		
subjects affected / exposed	11 / 8028 (0.14%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Forearm fracture		
subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured sacrum		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	13 / 8028 (0.16%)	9 / 8043 (0.11%)
occurrences causally related to treatment / all	0 / 13	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0
Heat stroke		

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hip fracture		
subjects affected / exposed	114 / 8028 (1.42%)	61 / 8043 (0.76%)
occurrences causally related to treatment / all	0 / 115	0 / 62
deaths causally related to treatment / all	0 / 1	0 / 0
Humerus fracture		
subjects affected / exposed	51 / 8028 (0.64%)	30 / 8043 (0.37%)
occurrences causally related to treatment / all	0 / 51	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Iliotibial band syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint dislocation		
subjects affected / exposed	7 / 8028 (0.09%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Laceration		
subjects affected / exposed	4 / 8028 (0.05%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Limb injury		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower limb fracture		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar vertebral fracture		

subjects affected / exposed	27 / 8028 (0.34%)	16 / 8043 (0.20%)
occurrences causally related to treatment / all	0 / 29	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 1
Meniscus injury		
subjects affected / exposed	3 / 8028 (0.04%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Periprosthetic fracture		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	10 / 8028 (0.12%)	11 / 8043 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	81 / 8028 (1.01%)	71 / 8043 (0.88%)
occurrences causally related to treatment / all	0 / 83	0 / 73
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	6 / 8028 (0.07%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	28 / 8028 (0.35%)	13 / 8043 (0.16%)
occurrences causally related to treatment / all	0 / 33	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		

subjects affected / exposed	23 / 8028 (0.29%)	13 / 8043 (0.16%)
occurrences causally related to treatment / all	0 / 23	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Ulna fracture		
subjects affected / exposed	28 / 8028 (0.35%)	17 / 8043 (0.21%)
occurrences causally related to treatment / all	0 / 28	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	7 / 8028 (0.09%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract stoma complication		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wrist fracture		
subjects affected / exposed	4 / 8028 (0.05%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wound dehiscence		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Acetabulum fracture		
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Animal bite		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic injury		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Arterial injury</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arterial restenosis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthropod bite</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Back injury</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder injury</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone contusion</b>		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone fissure</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiac valve rupture</b>		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chillblains		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Comminuted fracture		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Compression fracture		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	8 / 8028 (0.10%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Drug dispensing error		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extradural haematoma		

subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Face injury		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	2 / 8028 (0.02%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture displacement		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured ischium		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gun shot wound		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hand fracture		
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heat exhaustion		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heat illness		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Injury		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Jaw fracture		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Limb crushing injury		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb traumatic amputation</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mouth injury</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple injuries</b>		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Muscle injury</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle rupture</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle strain</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Patella fracture</b>		
subjects affected / exposed	11 / 8028 (0.14%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 11	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic fracture</b>		

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal injury		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural complication		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Post procedural discomfort		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural fistula		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural inflammation		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural oedema		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic neck syndrome		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative adhesion		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative hernia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural nausea		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary contusion</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rib fracture</b>		
subjects affected / exposed	10 / 8028 (0.12%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Road traffic accident</b>		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
<b>Scapula fracture</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scar</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skin abrasion</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Skull fractured base</b>		
subjects affected / exposed	0 / 8028 (0.00%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Soft tissue injury</b>		

subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Spinal compression fracture		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury cervical		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Splenic rupture		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Sternal injury		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous haematoma		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haemorrhage		

subjects affected / exposed	5 / 8028 (0.06%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Synovial rupture		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon injury		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tendon rupture		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemothorax		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic shock			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulnar nerve injury			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular injury			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 8028 (0.00%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound dehiscence			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrial septal defect			

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital bronchiectasis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital cystic kidney disease			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exomphalos			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	59 / 8028 (0.73%)	56 / 8043 (0.70%)	
occurrences causally related to treatment / all	0 / 64	2 / 58	
deaths causally related to treatment / all	0 / 14	0 / 16	
Angina pectoris			
subjects affected / exposed	44 / 8028 (0.55%)	40 / 8043 (0.50%)	
occurrences causally related to treatment / all	0 / 47	0 / 45	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	8 / 8028 (0.10%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 9	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 2	
Arrhythmia supraventricular			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arteriosclerosis coronary artery		
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	85 / 8028 (1.06%)	76 / 8043 (0.94%)
occurrences causally related to treatment / all	0 / 104	0 / 89
deaths causally related to treatment / all	0 / 3	0 / 2
Atrial flutter		
subjects affected / exposed	7 / 8028 (0.09%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	1 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	6 / 8028 (0.07%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 0
Bradycardia		
subjects affected / exposed	7 / 8028 (0.09%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	13 / 8028 (0.16%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 12	0 / 7
Cardiac disorder		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac failure		

subjects affected / exposed	44 / 8028 (0.55%)	37 / 8043 (0.46%)
occurrences causally related to treatment / all	0 / 47	0 / 40
deaths causally related to treatment / all	0 / 9	0 / 9
Cardiac failure chronic		
subjects affected / exposed	3 / 8028 (0.04%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac failure congestive		
subjects affected / exposed	36 / 8028 (0.45%)	39 / 8043 (0.48%)
occurrences causally related to treatment / all	2 / 38	0 / 40
deaths causally related to treatment / all	0 / 5	0 / 8
Cardio-respiratory arrest		
subjects affected / exposed	17 / 8028 (0.21%)	11 / 8043 (0.14%)
occurrences causally related to treatment / all	0 / 17	0 / 11
deaths causally related to treatment / all	0 / 14	0 / 11
Coronary artery disease		
subjects affected / exposed	32 / 8028 (0.40%)	32 / 8043 (0.40%)
occurrences causally related to treatment / all	1 / 35	0 / 35
deaths causally related to treatment / all	0 / 0	0 / 1
Hypertensive heart disease		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial infarction		
subjects affected / exposed	49 / 8028 (0.61%)	47 / 8043 (0.58%)
occurrences causally related to treatment / all	0 / 52	0 / 50
deaths causally related to treatment / all	0 / 19	0 / 16
Myocardial ischaemia		
subjects affected / exposed	15 / 8028 (0.19%)	19 / 8043 (0.24%)
occurrences causally related to treatment / all	0 / 15	0 / 21
deaths causally related to treatment / all	0 / 2	0 / 2
Sinus node dysfunction		

subjects affected / exposed	10 / 8028 (0.12%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Acute left ventricular failure		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Acute coronary syndrome		
subjects affected / exposed	9 / 8028 (0.11%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 10	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Adams-Stokes syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve disease		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Angina unstable		
subjects affected / exposed	34 / 8028 (0.42%)	34 / 8043 (0.42%)
occurrences causally related to treatment / all	1 / 37	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia		

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block first degree		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular dissociation		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	1 / 8028 (0.01%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block bilateral		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block right		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure acute		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Cardiac tamponade		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiac valve disease		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiac ventricular thrombosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiogenic shock		
subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 3	0 / 5
Cardiopulmonary failure		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Cardiovascular disorder		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Cardiovascular insufficiency		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Cor pulmonale acute		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery insufficiency		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery occlusion		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery perforation		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery stenosis		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cytotoxic cardiomyopathy		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heart valve incompetence		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive cardiomyopathy		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Left ventricular failure		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Microvascular coronary artery disease		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve disease		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Mitral valve incompetence		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Mitral valve stenosis		

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocarditis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Palpitations</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial effusion</b>		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pericardial haemorrhage</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Postinfarction angina</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Prinzmetal angina</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Right ventricular failure</b>		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Sinoatrial block</b>		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sinus bradycardia</b>		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Stress cardiomyopathy</b>		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Supraventricular extrasystoles</b>		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Supraventricular tachycardia</b>		
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tachyarrhythmia</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tachycardia</b>		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tachycardia paroxysmal</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ventricular arrhythmia</b>		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Ventricular dysfunction			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery occlusion			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral arteriosclerosis			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			

subjects affected / exposed	10 / 8028 (0.12%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 5	0 / 2
Cerebral infarction		
subjects affected / exposed	19 / 8028 (0.24%)	32 / 8043 (0.40%)
occurrences causally related to treatment / all	0 / 19	2 / 33
deaths causally related to treatment / all	0 / 1	0 / 2
Cerebral ischaemia		
subjects affected / exposed	9 / 8028 (0.11%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	46 / 8028 (0.57%)	72 / 8043 (0.90%)
occurrences causally related to treatment / all	1 / 47	2 / 72
deaths causally related to treatment / all	0 / 8	0 / 10
Cerebrovascular disorder		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular insufficiency		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Dizziness		
subjects affected / exposed	8 / 8028 (0.10%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 8	3 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy		

subjects affected / exposed	3 / 8028 (0.04%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Essential tremor		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiplegia		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	41 / 8028 (0.51%)	40 / 8043 (0.50%)
occurrences causally related to treatment / all	0 / 42	0 / 42
deaths causally related to treatment / all	0 / 4	0 / 4
Lacunar infarction		
subjects affected / exposed	9 / 8028 (0.11%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Myelitis transverse		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Radicular syndrome		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Radiculopathy</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sciatic nerve palsy</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Syncope</b>		
subjects affected / exposed	20 / 8028 (0.25%)	32 / 8043 (0.40%)
occurrences causally related to treatment / all	0 / 20	0 / 35
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Transient ischaemic attack</b>		
subjects affected / exposed	35 / 8028 (0.44%)	34 / 8043 (0.42%)
occurrences causally related to treatment / all	0 / 38	2 / 37
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular encephalopathy</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Altered state of consciousness</b>		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Amyotrophic lateral sclerosis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Apallic syndrome</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Aphasia</b>		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ataxia</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Basal ganglia haemorrhage</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Basal ganglia infarction</b>		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain injury</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Brain oedema</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain stem infarction</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain stem stroke</b>		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid arteriosclerosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery aneurysm		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery disease		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery thrombosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid sinus syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carpal tunnel syndrome		
subjects affected / exposed	5 / 8028 (0.06%)	9 / 8043 (0.11%)
occurrences causally related to treatment / all	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral artery embolism		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral circulatory failure		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral thrombosis		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral venous thrombosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical myelopathy		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Complex partial seizures		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cranial nerve disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dementia Alzheimer's type		
subjects affected / exposed	4 / 8028 (0.05%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 1
Depressed level of consciousness		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyslalia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic cerebral infarction		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Encephalopathy		

subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Frontotemporal dementia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Guillain-Barre syndrome		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhage intracranial		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Haemorrhagic stroke		
subjects affected / exposed	6 / 8028 (0.07%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 2	0 / 8
Headache		
subjects affected / exposed	4 / 8028 (0.05%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	1 / 4	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		

subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotonia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
IIIrd nerve paralysis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Intracranial haematoma		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial venous sinus thrombosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic neuropathy		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Loss of consciousness		
subjects affected / exposed	8 / 8028 (0.10%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Memory impairment		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningorrhagia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic encephalopathy		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Migraine		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Morton's neuralgia		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myasthenia gravis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve compression		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neuritis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Neuropathy peripheral		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Normal pressure hydrocephalus		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraesthesia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paraparesis		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parkinsonism</b>		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Partial seizures</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peripheral nerve lesion</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peripheral sensorimotor neuropathy</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polyneuropathy</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Post herpetic neuralgia</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Presyncope</b>		
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ruptured cerebral aneurysm</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Sciatica</b>		
subjects affected / exposed	6 / 8028 (0.07%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sedation</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Seizure</b>		
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sensory disturbance</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Senile dementia</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Slow speech</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Status epilepticus</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subarachnoid haemorrhage</b>		

subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1
Thrombotic stroke		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Thalamus haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Trigeminal neuralgia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
VIIth nerve paralysis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery stenosis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		

subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
White matter lesion			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	22 / 8028 (0.27%)	16 / 8043 (0.20%)	
occurrences causally related to treatment / all	0 / 23	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia megaloblastic			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aplastic anaemia			

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Autoimmune haemolytic anaemia</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coagulopathy</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Febrile neutropenia</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhagic diathesis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhagic disorder</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypochromic anaemia</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Immune thrombocytopenic purpura</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lymphadenitis</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pernicious anaemia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden hearing loss			

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo		
subjects affected / exposed	5 / 8028 (0.06%)	16 / 8043 (0.20%)
occurrences causally related to treatment / all	0 / 5	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo positional		
subjects affected / exposed	2 / 8028 (0.02%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Acute vestibular syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
External ear disorder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Inner ear disorder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meniere's disease		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Neurosensory hypoacusis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Otosclerosis		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tinnitus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tympanic membrane perforation			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	84 / 8028 (1.05%)	99 / 8043 (1.23%)	
occurrences causally related to treatment / all	0 / 114	0 / 133	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract subcapsular			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal tear			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal vein thrombosis			

subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Age-related macular degeneration		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Amaurosis fugax		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Angle closure glaucoma		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blindness		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blindness unilateral		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chalazion		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Choroiditis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ciliary body disorder		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Conjunctival haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Corneal opacity		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystoid macular oedema		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dacryostenosis acquired		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diplopia		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Entropion		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Excessive eye blinking		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid ptosis		

subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Glaucoma</b>		
subjects affected / exposed	3 / 8028 (0.04%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Iritis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Keratitis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Keratitis interstitial</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Keratopathy</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lacrimal disorder</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lens disorder</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Macular degeneration</b>		

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Macular fibrosis</b>		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Macular hole</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Maculopathy</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myopia</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neovascular age-related macular degeneration</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Optic atrophy</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Optic ischaemic neuropathy</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Posterior capsule opacification</b>		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal artery embolism</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal degeneration</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal detachment</b>		
subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal dystrophy</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal haemorrhage</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal vein occlusion</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinopathy</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Trichiasis</b>		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vision blurred			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual acuity reduced			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	11 / 8028 (0.14%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal prolapse			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			

subjects affected / exposed	7 / 8028 (0.09%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	10 / 8028 (0.12%)	9 / 8043 (0.11%)
occurrences causally related to treatment / all	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	3 / 8028 (0.04%)	9 / 8043 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterovesical fistula		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Faecaloma		
subjects affected / exposed	6 / 8028 (0.07%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric disorder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		

subjects affected / exposed	9 / 8028 (0.11%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Gastroduodenitis</b>		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrooesophageal reflux disease</b>		
subjects affected / exposed	10 / 8028 (0.12%)	10 / 8043 (0.12%)
occurrences causally related to treatment / all	0 / 10	1 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hiatus hernia</b>		
subjects affected / exposed	8 / 8028 (0.10%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus</b>		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Inguinal hernia</b>		
subjects affected / exposed	12 / 8028 (0.15%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intestinal obstruction</b>		
subjects affected / exposed	11 / 8028 (0.14%)	11 / 8043 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 13
deaths causally related to treatment / all	0 / 2	0 / 2
<b>Irritable bowel syndrome</b>		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower gastrointestinal haemorrhage</b>		

subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis acute		
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatitis chronic		
subjects affected / exposed	7 / 8028 (0.09%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Upper gastrointestinal haemorrhage		
subjects affected / exposed	12 / 8028 (0.15%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 12	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 1
Abdominal adhesions		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal distension		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal hernia obstructive		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Abdominal pain lower		

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	2 / 8028 (0.02%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 2	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Anal fissure		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal inflammation		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal stenosis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Barrett's oesophagus		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Change of bowel habit		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastritis		
subjects affected / exposed	5 / 8028 (0.06%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis		
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 6	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis microscopic		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ulcerative		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	10 / 8028 (0.12%)	9 / 8043 (0.11%)
occurrences causally related to treatment / all	1 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Crohn's disease		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dental caries		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea		

subjects affected / exposed	8 / 8028 (0.10%)	12 / 8043 (0.15%)
occurrences causally related to treatment / all	0 / 9	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum oesophageal		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dolichocolon acquired		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal perforation		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Duodenal ulcer		
subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer perforation		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Duodenitis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysbacteriosis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dyspepsia		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dysphagia		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocoele		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocutaneous fistula		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Erosive oesophagitis		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Faecal incontinence		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral hernia incarcerated		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Functional gastrointestinal disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric antral vascular ectasia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 4	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Gastritis		
subjects affected / exposed	10 / 8028 (0.12%)	19 / 8043 (0.24%)
occurrences causally related to treatment / all	1 / 11	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	7 / 8028 (0.09%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 1
Gastrointestinal inflammation		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal motility disorder		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal necrosis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal obstruction		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoidal haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids		
subjects affected / exposed	10 / 8028 (0.12%)	11 / 8043 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhoids thrombosed		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hernial eventration		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ileus paralytic		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Incarcerated umbilical hernia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal mass		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal perforation		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Intestinal polyp		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal prolapse		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Intussusception</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ischiorectal hernia</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Large intestine perforation</b>		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Large intestine polyp</b>		
subjects affected / exposed	10 / 8028 (0.12%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	1 / 10	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar hernia</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mallory-Weiss syndrome</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Mechanical ileus</b>		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Melaena</b>		

subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Mesenteric artery embolism		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mouth cyst		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mouth ulceration		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nausea		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Obstruction gastric		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal achalasia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal fistula		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal hypomotility		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal pain		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal stenosis		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal varices haemorrhage		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis ulcerative		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oral pain		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic cyst		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic pseudocyst		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatitis</b>		
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pancreatitis necrotising</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Peptic ulcer</b>		
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peptic ulcer haemorrhage</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peptic ulcer perforation</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pharyngo-oesophageal diverticulum</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal haemorrhage</b>		
subjects affected / exposed	1 / 8028 (0.01%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Rectal polyp</b>		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal prolapse</b>		
subjects affected / exposed	3 / 8028 (0.04%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Salivary gland calculus</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Small intestinal obstruction</b>		
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splenic artery aneurysm</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stomach mass</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subileus</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thrombosis mesenteric vessel</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Toothache</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Volvulus			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	6 / 8028 (0.07%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	5 / 8028 (0.06%)	11 / 8043 (0.14%)	
occurrences causally related to treatment / all	0 / 5	0 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	15 / 8028 (0.19%)	21 / 8043 (0.26%)	
occurrences causally related to treatment / all	0 / 15	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			

subjects affected / exposed	39 / 8028 (0.49%)	34 / 8043 (0.42%)
occurrences causally related to treatment / all	0 / 43	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Bile duct obstruction		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct stenosis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary fistula		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis acute		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		

subjects affected / exposed	15 / 8028 (0.19%)	7 / 8043 (0.09%)
occurrences causally related to treatment / all	0 / 15	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Cholecystitis chronic		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder disorder		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder polyp		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cyst		
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic failure		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic steatosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis cholestatic			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatorenal failure			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Jaundice			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Liver disorder			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-alcoholic steatohepatitis			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Decubitus ulcer			

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Skin necrosis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Subacute cutaneous lupus erythematosus</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Actinic keratosis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Acute generalised exanthematous pustulosis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Angioedema</b>		
subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Blister</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dermal cyst</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dermatitis</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis allergic		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis atopic		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatitis contact		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dermatomyositis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema multiforme		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema nodosum		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hand dermatitis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Henoch-Schonlein purpura</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyperkeratosis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypersensitivity vasculitis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lentigo</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lichen sclerosus</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurodermatitis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pemphigoid</b>		

subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pruritus generalised		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyoderma gangrenosum		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash erythematous		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash generalised		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin ulcer		
subjects affected / exposed	6 / 8028 (0.07%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Skin wrinkling		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urticaria		

subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 3	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Renal and urinary disorders</b>			
<b>Acute kidney injury</b>			
subjects affected / exposed	7 / 8028 (0.09%)	7 / 8043 (0.09%)	
occurrences causally related to treatment / all	0 / 7	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 2	
<b>Bladder prolapse</b>			
subjects affected / exposed	7 / 8028 (0.09%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nephrolithiasis</b>			
subjects affected / exposed	11 / 8028 (0.14%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 11	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nephropathy</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Renal artery stenosis</b>			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ureteric stenosis</b>			
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Acute prerenal failure</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Azotaemia</b>			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder cyst		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder diverticulum		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder irritation		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder perforation		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus ureteric		
subjects affected / exposed	5 / 8028 (0.06%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urinary		

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	1 / 8028 (0.01%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	1 / 3
Cystitis haemorrhagic		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Glomerulonephritis membranous		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulonephritis rapidly progressive		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	5 / 8028 (0.06%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertonic bladder		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oliguria		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pollakiuria		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	4 / 8028 (0.05%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 1
Renal impairment		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal tubular disorder		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Scleroderma renal crisis		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Stress urinary incontinence</b>		
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Tubulointerstitial nephritis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urethral caruncle</b>		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urethral polyp</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urethral stenosis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary bladder polyp</b>		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary incontinence</b>		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Urinary retention</b>		

subjects affected / exposed	4 / 8028 (0.05%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Endocrine disorders</b>			
<b>Goitre</b>			
subjects affected / exposed	7 / 8028 (0.09%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 7	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperparathyroidism</b>			
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperparathyroidism primary</b>			
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperthyroidism</b>			
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Toxic nodular goitre</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Adrenal haemorrhage</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Adrenal insufficiency</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Autoimmune thyroiditis</b>			

subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperadrenalism			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary hypothyroidism			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Secondary hyperthyroidism			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cyst			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroiditis subacute			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	8 / 8028 (0.10%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 8	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot deformity			
subjects affected / exposed	10 / 8028 (0.12%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 11	0 / 16	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture delayed union			
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemarthrosis			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	11 / 8028 (0.14%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 11	0 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	8 / 8028 (0.10%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 8028 (0.01%)	8 / 8043 (0.10%)	
occurrences causally related to treatment / all	0 / 1	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal pain			
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			

subjects affected / exposed	123 / 8028 (1.53%)	147 / 8043 (1.83%)
occurrences causally related to treatment / all	0 / 141	0 / 167
deaths causally related to treatment / all	0 / 0	0 / 0
Polyarthritis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rotator cuff syndrome		
subjects affected / exposed	12 / 8028 (0.15%)	18 / 8043 (0.22%)
occurrences causally related to treatment / all	0 / 13	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal osteoarthritis		
subjects affected / exposed	8 / 8028 (0.10%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Spondylolisthesis		
subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Systemic lupus erythematosus		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis		
subjects affected / exposed	8 / 8028 (0.10%)	12 / 8043 (0.15%)
occurrences causally related to treatment / all	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Atlantoaxial instability		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Axillary mass		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Back pain</b>		
subjects affected / exposed	22 / 8028 (0.27%)	20 / 8043 (0.25%)
occurrences causally related to treatment / all	0 / 22	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone loss</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone pain</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bursitis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chondrocalcinosis pyrophosphate</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Chondropathy</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Connective tissue disorder</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Costochondritis</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dupuytren's contracture		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Eosinophilic fasciitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facet joint syndrome		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture malunion		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture pain		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc space narrowing		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaw cyst		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint adhesion		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint contracture		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint range of motion decreased		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint stiffness		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Joint swelling		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Knee deformity		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mobility decreased		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Monarthritis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Morphoea</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscle spasms</b>		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Muscular weakness</b>		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia</b>		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nodal osteoarthritis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteochondritis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteochondrosis</b>		

subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteonecrosis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteosclerosis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain in extremity</b>		
subjects affected / exposed	1 / 8028 (0.01%)	9 / 8043 (0.11%)
occurrences causally related to treatment / all	0 / 1	2 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periarthritis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Periostitis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Plantar fasciitis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Polymyalgia rheumatica</b>		
subjects affected / exposed	5 / 8028 (0.06%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rheumatoid arthritis</b>		

subjects affected / exposed	7 / 8028 (0.09%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scleroderma</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scoliosis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sjogren's syndrome</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Soft tissue necrosis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal column stenosis</b>		
subjects affected / exposed	17 / 8028 (0.21%)	15 / 8043 (0.19%)
occurrences causally related to treatment / all	0 / 17	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal pain</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondylitis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spondyloarthropathy</b>		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Synovial cyst</b>			
subjects affected / exposed	1 / 8028 (0.01%)	6 / 8043 (0.07%)	
occurrences causally related to treatment / all	0 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Synovitis</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tendonitis</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tenosynovitis stenosaurs</b>			
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Trigger finger</b>			
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ulnocarpal abutment syndrome</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Appendiceal abscess</b>			
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Appendicitis</b>			

subjects affected / exposed	13 / 8028 (0.16%)	20 / 8043 (0.25%)
occurrences causally related to treatment / all	0 / 13	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		
subjects affected / exposed	16 / 8028 (0.20%)	16 / 8043 (0.20%)
occurrences causally related to treatment / all	0 / 17	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchopneumonia</b>		
subjects affected / exposed	17 / 8028 (0.21%)	19 / 8043 (0.24%)
occurrences causally related to treatment / all	0 / 18	0 / 20
deaths causally related to treatment / all	0 / 5	0 / 7
<b>Cellulitis</b>		
subjects affected / exposed	16 / 8028 (0.20%)	17 / 8043 (0.21%)
occurrences causally related to treatment / all	0 / 20	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis</b>		
subjects affected / exposed	29 / 8028 (0.36%)	35 / 8043 (0.44%)
occurrences causally related to treatment / all	0 / 31	0 / 35
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Gastroenteritis Escherichia coli</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastrointestinal viral infection</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Herpes zoster</b>		
subjects affected / exposed	5 / 8028 (0.06%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Infective exacerbation of chronic obstructive airways disease</b>		

subjects affected / exposed	8 / 8028 (0.10%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	11 / 8028 (0.14%)	15 / 8043 (0.19%)
occurrences causally related to treatment / all	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 2	0 / 2
Peritonitis		
subjects affected / exposed	6 / 8028 (0.07%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 4
Pneumonia		
subjects affected / exposed	128 / 8028 (1.59%)	119 / 8043 (1.48%)
occurrences causally related to treatment / all	0 / 133	0 / 138
deaths causally related to treatment / all	0 / 24	0 / 23
Pulmonary sepsis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	8 / 8028 (0.10%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	3 / 8028 (0.04%)	5 / 8043 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory tract infection		

subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sepsis</b>		
subjects affected / exposed	19 / 8028 (0.24%)	23 / 8043 (0.29%)
occurrences causally related to treatment / all	0 / 20	0 / 24
deaths causally related to treatment / all	0 / 10	0 / 14
<b>Urinary tract infection</b>		
subjects affected / exposed	54 / 8028 (0.67%)	54 / 8043 (0.67%)
occurrences causally related to treatment / all	1 / 64	1 / 58
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Wound infection</b>		
subjects affected / exposed	8 / 8028 (0.10%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal abscess</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal sepsis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Abdominal wall abscess</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess limb</b>		

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess neck</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Acute sinusitis</b>		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Amoebic colitis</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Appendicitis perforated</b>		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthritis bacterial</b>		
subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Arthritis infective</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacteraemia</b>		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Beta haemolytic streptococcal infection</b>		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burn infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carbuncle		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Catheter site infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Central nervous system viral infection		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chlamydial infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		

subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cutaneous tuberculosis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	8 / 8028 (0.10%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	1 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dacryocystitis		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	5 / 8028 (0.06%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Device related infection		

subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diarrhoea infectious		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	20 / 8028 (0.25%)	25 / 8043 (0.31%)
occurrences causally related to treatment / all	0 / 22	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 1
Dysentery		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endophthalmitis		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter pneumonia		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Erysipelas		
subjects affected / exposed	5 / 8028 (0.06%)	6 / 8043 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Erythema migrans		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Escherichia urinary tract infection		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder empyema		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gangrene		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Gastritis viral		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis bacterial		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis clostridial		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis rotavirus		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis salmonella		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Graft infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter infection		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis E		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes simplex encephalitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Herpes zoster infection neurological		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Implant site infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bites		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected dermal cyst		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infected varicose vein		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Influenza		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal fistula infection		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Keratitis bacterial		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Labyrinthitis		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngitis		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Lobar pneumonia		
subjects affected / exposed	12 / 8028 (0.15%)	11 / 8043 (0.14%)
occurrences causally related to treatment / all	0 / 12	0 / 11
deaths causally related to treatment / all	0 / 3	0 / 2
Lower respiratory tract infection bacterial		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	5 / 8028 (0.06%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malaria		
subjects affected / exposed	4 / 8028 (0.05%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinitis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Meningitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis bacterial		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neurosyphilis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neutropenic sepsis</b>		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal candidiasis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oral candidiasis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis</b>		
subjects affected / exposed	3 / 8028 (0.04%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreatic abscess</b>		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parotitis</b>		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pelvic sepsis</b>		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital cellulitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngitis		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngotonsillitis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia bacterial		
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia necrotising		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pneumonia pneumococcal		

subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	2 / 8028 (0.02%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	5 / 8028 (0.06%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomembranous colitis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudomonal bacteraemia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary echinococcosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary tuberculosis		
subjects affected / exposed	1 / 8028 (0.01%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	1 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelocystitis		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis chronic		
subjects affected / exposed	0 / 8028 (0.00%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pyometra		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pyonephrosis		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal abscess		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Respiratory syncytial virus infection		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salmonellosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	7 / 8028 (0.09%)	12 / 8043 (0.15%)
occurrences causally related to treatment / all	0 / 7	0 / 12
deaths causally related to treatment / all	0 / 5	0 / 10
Sialoadenitis		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinobronchitis		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin infection		
subjects affected / exposed	2 / 8028 (0.02%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal bacteraemia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal skin infection		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stoma site abscess		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		

subjects affected / exposed	4 / 8028 (0.05%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subdiaphragmatic abscess		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tick-borne fever		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Tooth infection		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	0 / 8028 (0.00%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection pseudomonal		

subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	4 / 8028 (0.05%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 1
Vaginal abscess		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular neuronitis		
subjects affected / exposed	2 / 8028 (0.02%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Viral labyrinthitis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral upper respiratory tract infection		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection staphylococcal		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound sepsis		

subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Metabolism and nutrition disorders</b>			
<b>Dehydration</b>			
subjects affected / exposed	7 / 8028 (0.09%)	14 / 8043 (0.17%)	
occurrences causally related to treatment / all	0 / 7	0 / 14	
deaths causally related to treatment / all	0 / 1	0 / 1	
<b>Folate deficiency</b>			
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypoglycaemia</b>			
subjects affected / exposed	7 / 8028 (0.09%)	10 / 8043 (0.12%)	
occurrences causally related to treatment / all	0 / 7	0 / 11	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Hyponatraemia</b>			
subjects affected / exposed	16 / 8028 (0.20%)	9 / 8043 (0.11%)	
occurrences causally related to treatment / all	0 / 17	0 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cachexia</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Decreased appetite</b>			
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetes mellitus</b>			
subjects affected / exposed	10 / 8028 (0.12%)	5 / 8043 (0.06%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Diabetes mellitus inadequate control</b>			

subjects affected / exposed	9 / 8028 (0.11%)	8 / 8043 (0.10%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	2 / 8028 (0.02%)	4 / 8043 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Electrolyte imbalance		
subjects affected / exposed	2 / 8028 (0.02%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Gout		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	3 / 8028 (0.04%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	1 / 8028 (0.01%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperosmolar state		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypokalaemia		

subjects affected / exposed	3 / 8028 (0.04%)	3 / 8043 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Hypophagia		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemia		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Ketoacidosis		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malnutrition		
subjects affected / exposed	1 / 8028 (0.01%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Metabolic acidosis		
subjects affected / exposed	0 / 8028 (0.00%)	1 / 8043 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metabolic disorder		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Type 1 diabetes mellitus		
subjects affected / exposed	1 / 8028 (0.01%)	0 / 8043 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Type 2 diabetes mellitus		

subjects affected / exposed	3 / 8028 (0.04%)	2 / 8043 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0

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

<b>Non-serious adverse events</b>	Participants Who Had Received Placebo During the 018 Study	Participants Who Had Received Odanacatib During the 018 Study	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5525 / 8028 (68.82%)	5577 / 8043 (69.34%)	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	424 / 8028 (5.28%)	388 / 8043 (4.82%)	
occurrences (all)	572	502	
Vascular disorders			
Hypertension			
subjects affected / exposed	1093 / 8028 (13.61%)	1110 / 8043 (13.80%)	
occurrences (all)	1288	1270	
Nervous system disorders			
Dizziness			
subjects affected / exposed	485 / 8028 (6.04%)	495 / 8043 (6.15%)	
occurrences (all)	567	577	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	502 / 8028 (6.25%)	477 / 8043 (5.93%)	
occurrences (all)	586	552	
Eye disorders			
Cataract			
subjects affected / exposed	501 / 8028 (6.24%)	494 / 8043 (6.14%)	
occurrences (all)	664	646	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	508 / 8028 (6.33%)	494 / 8043 (6.14%)	
occurrences (all)	556	549	
Diarrhoea			

subjects affected / exposed occurrences (all)	504 / 8028 (6.28%) 608	591 / 8043 (7.35%) 728	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	469 / 8028 (5.84%) 552	471 / 8043 (5.86%) 553	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1155 / 8028 (14.39%) 1541	1223 / 8043 (15.21%) 1590	
Back pain subjects affected / exposed occurrences (all)	1139 / 8028 (14.19%) 1400	1200 / 8043 (14.92%) 1480	
Musculoskeletal pain subjects affected / exposed occurrences (all)	464 / 8028 (5.78%) 542	519 / 8043 (6.45%) 590	
Osteoarthritis subjects affected / exposed occurrences (all)	752 / 8028 (9.37%) 926	794 / 8043 (9.87%) 992	
Pain in extremity subjects affected / exposed occurrences (all)	675 / 8028 (8.41%) 802	753 / 8043 (9.36%) 925	
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	461 / 8028 (5.74%) 615	452 / 8043 (5.62%) 600	
Influenza subjects affected / exposed occurrences (all)	443 / 8028 (5.52%) 565	497 / 8043 (6.18%) 613	
Nasopharyngitis subjects affected / exposed occurrences (all)	940 / 8028 (11.71%) 1368	957 / 8043 (11.90%) 1397	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	600 / 8028 (7.47%) 919	646 / 8043 (8.03%) 968	

Urinary tract infection subjects affected / exposed occurrences (all)	1702 / 8028 (21.20%) 2831	1729 / 8043 (21.50%) 2921	
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## **More information**

### **Substantial protocol amendments (globally)**

Were there any global substantial amendments to the protocol? No

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### **Interruptions (globally)**

Were there any global interruptions to the trial? No

### **Limitations and caveats**

None reported