



## Clinical trial results:

### A Multinational, Randomised, Double-Blind, Placebo-Controlled Trial to Evaluate the Effect of Ticagrelor twice daily on the Incidence of Cardiovascular Death, Myocardial Infarction or Stroke in Patients with Type 2 Diabetes Mellitus

#### Summary

EudraCT number	2013-003519-23
Trial protocol	HU CZ SK SE NL DE IT GB ES NO AT DK BE FI BG FR
Global end of trial date	16 February 2019

#### Results information

Result version number	v1
This version publication date	26 January 2020
First version publication date	26 January 2020

#### Trial information

##### Trial identification

Sponsor protocol code	D513BC00001
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01991795
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	Pepparedsleden 1, Mölndal, Sweden, 43183
Public contact	Global Clinical Lead, Study Information center, +1 877 240 9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, Study Information center, +1 877 240 9479, information.center@astrazeneca.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	16 February 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 February 2019
Global end of trial reached?	Yes
Global end of trial date	16 February 2019
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of the study is to compare the effect of long-term treatment with ticagrelor twice daily (bd) vs. placebo for the prevention of major cardiovascular (CV) events (composite of CV death, myocardial infarction [MI] or stroke) in patients with Type 2 Diabetes Mellitus (T2DM) at high risk for CV events, but without a previous medical history of MI or stroke. The primary efficacy variable is time from randomisation to first occurrence of any event from the composite of CV death, MI or stroke (ischaemic, haemorrhagic or unknown etiology).

Protection of trial subjects:

Treated in routine care, on a background therapy of acetylsalicylic acid (ASA).

Background therapy:

Patients should be treated with low-dose acetylsalicylic acid (ASA) unless contraindicated or not tolerated, in accordance with national and international clinical practice guidelines.

Evidence for comparator: -

Actual start date of recruitment	10 February 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	40 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 1636
Country: Number of subjects enrolled	Russian Federation: 1121
Country: Number of subjects enrolled	Argentina: 394
Country: Number of subjects enrolled	Australia: 188
Country: Number of subjects enrolled	Austria: 87
Country: Number of subjects enrolled	Belgium: 217
Country: Number of subjects enrolled	Bulgaria: 878
Country: Number of subjects enrolled	Brazil: 811
Country: Number of subjects enrolled	Canada: 729
Country: Number of subjects enrolled	Chile: 300
Country: Number of subjects enrolled	China: 910
Country: Number of subjects enrolled	Colombia: 136
Country: Number of subjects enrolled	Czech Republic: 602
Country: Number of subjects enrolled	Denmark: 243
Country: Number of subjects enrolled	Germany: 547

Country: Number of subjects enrolled	Spain: 340
Country: Number of subjects enrolled	Finland: 118
Country: Number of subjects enrolled	France: 172
Country: Number of subjects enrolled	United Kingdom: 246
Country: Number of subjects enrolled	Hong Kong: 152
Country: Number of subjects enrolled	Hungary: 616
Country: Number of subjects enrolled	India: 292
Country: Number of subjects enrolled	Israel: 117
Country: Number of subjects enrolled	Italy: 130
Country: Number of subjects enrolled	Japan: 496
Country: Number of subjects enrolled	Korea, Republic of: 870
Country: Number of subjects enrolled	Mexico: 364
Country: Number of subjects enrolled	Netherlands: 479
Country: Number of subjects enrolled	Norway: 191
Country: Number of subjects enrolled	Peru: 173
Country: Number of subjects enrolled	Philippines: 92
Country: Number of subjects enrolled	Romania: 80
Country: Number of subjects enrolled	Saudi Arabia: 155
Country: Number of subjects enrolled	Slovakia: 244
Country: Number of subjects enrolled	Thailand: 231
Country: Number of subjects enrolled	Turkey: 225
Country: Number of subjects enrolled	Sweden: 224
Country: Number of subjects enrolled	Taiwan: 803
Country: Number of subjects enrolled	Ukraine: 792
Country: Number of subjects enrolled	United States: 2266
Country: Number of subjects enrolled	Vietnam: 254
Country: Number of subjects enrolled	South Africa: 299
Worldwide total number of subjects	19220
EEA total number of subjects	7050

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)	7934
From 65 to 84 years	11115
85 years and over	171

## Subject disposition

### Recruitment

Recruitment details:

In total, 20108 patients were enrolled, 19220 patients were randomised to study drug and included in the analyses, from 1315 study sites in 42 countries. The first patient was enrolled on 10 February 2014. The last patient visit took place on 25 January 2019.

### Pre-assignment

Screening details:

Enrolled patients randomised to study drug 95.8%; n =19271, of which 51 patients were randomised to study drug at a site prematurely closed by sponsor and excluded from the study results. Patients who were not randomised 4.2%; n=837. Patient did not meet inclusion/exclusion criteria n=454, Patient decision n=256, Death n=1, Other reason n=131.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Ticagrelor 60 mg

Arm description:

Initially ticagrelor 90 mg or corresponding placebo was the selected dose, but reduced to ticagrelor 60 mg or corresponding placebo in Clinical Study Protocol Amendment No 1.

Arm type	Experimental
Investigational medicinal product name	Ticagrelor 60mg film-coated tablets
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

60 mg twice daily

Investigational medicinal product name	Ticagrelor 90mg film-coated tablets
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

90 mg twice daily

<b>Arm title</b>	Ticagrelor placebo
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Arm description:

Initially ticagrelor 90 mg or corresponding placebo was the selected dose, but reduced to ticagrelor 60 mg or corresponding placebo in Clinical Study Protocol Amendment No 1.

Arm type	Placebo
Investigational medicinal product name	Ticagrelor 90 mg placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Matching 90mg ticagrelor placebo twice daily

Investigational medicinal product name	Ticagrelor 60 mg placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Matching 60mg ticagrelor placebo twice daily

<b>Number of subjects in period 1</b>	Ticagrelor 60 mg	Ticagrelor placebo
Started	9619	9601
Completed	9496	9503
Not completed	123	98
Consent withdrawn by subject	117	94
Lost to follow-up	6	4

## Baseline characteristics

### Reporting groups

Reporting group title	Ticagrelor 60 mg
Reporting group description: Initially ticagrelor 90 mg or corresponding placebo was the selected dose, but reduced to ticagrelor 60 mg or corresponding placebo in Clinical Study Protocol Amendment No 1.	
Reporting group title	Ticagrelor placebo
Reporting group description: Initially ticagrelor 90 mg or corresponding placebo was the selected dose, but reduced to ticagrelor 60 mg or corresponding placebo in Clinical Study Protocol Amendment No 1.	

Reporting group values	Ticagrelor 60 mg	Ticagrelor placebo	Total
Number of subjects	9619	9601	19220
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)	3975	3959	7934
From 65-84 years	5560	5555	11115
85 years and over	84	87	171
Age Continuous			
Units: Years			
arithmetic mean	66.3	66.3	
standard deviation	± 7.8	± 7.7	-
Sex: Female, Male			
Units: Subjects			
Male	6576	6613	13189
Female	3043	2988	6031
Region of Enrollment			
Units: Subjects			
ARG	195	199	394
AUS	94	94	188
AUT	42	45	87
BEL	109	108	217
BGR	435	443	878
BRA	412	399	811
CAN	364	365	729
CHL	152	148	300
CHN	456	454	910
COL	68	68	136
CZE	304	298	602
DEU	277	270	547
DNK	123	120	243

ESP	170	170	340
FIN	60	58	118
FRA	85	87	172
GBR	123	123	246
HKG	76	76	152
HUN	306	310	616
IND	147	145	292
ISR	60	57	117
ITA	67	63	130
JPN	246	250	496
KOR	433	437	870
MEX	182	182	364
NLD	242	237	479
NOR	95	96	191
PER	91	82	173
PHL	47	45	92
POL	815	821	1636
ROU	37	43	80
RUS	561	560	1121
SAU	79	76	155
SVK	122	122	244
SWE	110	114	224
THA	115	116	231
TUR	113	112	225
TWN	402	401	803
UKR	399	393	792
USA	1126	1140	2266
VNM	129	125	254
ZAF	150	149	299
Race/Ethnicity, Customized			
Units: Subjects			
White	6838	6858	13696
Black or african american	205	198	403
Asian	2211	2195	4406
Native hawaiian or other pacific islander	7	7	14
American indian or alaska native	161	152	313
Other	197	191	388

## End points

### End points reporting groups

Reporting group title	Ticagrelor 60 mg
Reporting group description: Initially ticagrelor 90 mg or corresponding placebo was the selected dose, but reduced to ticagrelor 60 mg or corresponding placebo in Clinical Study Protocol Amendment No 1.	
Reporting group title	Ticagrelor placebo
Reporting group description: Initially ticagrelor 90 mg or corresponding placebo was the selected dose, but reduced to ticagrelor 60 mg or corresponding placebo in Clinical Study Protocol Amendment No 1.	

### Primary: Time from randomisation to first occurrence of any event from the composite of CV death, MI or stroke

End point title	Time from randomisation to first occurrence of any event from the composite of CV death, MI or stroke
End point description: Participants with Cardiovascular (CV) death, myocardial infarction (MI) or stroke. If no event, censoring occurs at the earliest of PACD, last endpoint assessment date and non-CV death date.	
End point type	Primary
End point timeframe: From randomisation to primary analysis censoring date (PACD), a median of 40 months	

End point values	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9619	9601		
Units: Participants	736	818		

### Statistical analyses

Statistical analysis title	Prevention of composite of CV death, MI or stroke
Statistical analysis description: Time to first occurrence of any event from the composite of CV death, MI or stroke.	
Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
Number of subjects included in analysis	19220
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0378 <sup>[1]</sup>
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	0.99

Notes:

[1] - The hypothesis will be tested at the 4.96% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

### Secondary: Prevention of CV death. The efficacy variable is time from randomisation to death of CV cause

End point title	Prevention of CV death. The efficacy variable is time from randomisation to death of CV cause
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End point description:

Participants with Cardiovascular (CV) death. If no event, censoring occurs at the earliest of PACD, last endpoint assessment date and non-CV death date.

End point type	Secondary
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End point timeframe:

From randomisation to primary analysis censoring date (PACD)

End point values	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9619	9601		
Units: Participants	364	357		

### Statistical analyses

Statistical analysis title	Prevention of CV death
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Statistical analysis description:

Time from randomisation to death of CV cause

Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
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Number of subjects included in analysis	19220
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Analysis specification	Pre-specified
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Analysis type	superiority
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P-value	= 0.7883 [2]
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Method	Regression, Cox
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Parameter estimate	Hazard ratio (HR)
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Point estimate	1.02
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	0.88
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upper limit	1.18
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Notes:

[2] - The hypothesis will be tested at the 4.96% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

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**Secondary: Prevention of MI. The efficacy variable is time from randomisation to first occurrence of MI**

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End point title	Prevention of MI. The efficacy variable is time from randomisation to first occurrence of MI
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End point description:

Participants with myocardial infarction. If no event, censoring occurs at the earliest of primary analysis censoring date (PACD), last endpoint assessment date and death date

End point type	Secondary
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End point timeframe:

From randomisation to primary analysis censoring date (PACD)

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End point values	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9619	9601		
Units: Participants	274	328		

**Statistical analyses**

Statistical analysis title	Prevention of MI
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Statistical analysis description:

Time from randomisation to first occurrence of MI.

Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
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Number of subjects included in analysis	19220
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Analysis specification	Pre-specified
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Analysis type	superiority
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P-value	= 0.0294 [3]
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Method	Regression, Cox
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Parameter estimate	Hazard ratio (HR)
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Point estimate	0.84
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Confidence interval	
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level	95 %
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sides	2-sided
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lower limit	0.71
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upper limit	0.98
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Notes:

[3] - The hypothesis will be tested at the 4.96% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

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**Secondary: Prevention of ischaemic stroke. The efficacy variable is time from randomisation to first occurrence of ischaemic stroke**

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End point title	Prevention of ischaemic stroke. The efficacy variable is time from randomisation to first occurrence of ischaemic stroke
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End point description:

Participants with ischaemic stroke. If no event, censoring occurs at the earliest of PACD, last endpoint assessment date and death date.

End point type	Secondary
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End point timeframe:

From randomisation to primary analysis censoring date (PACD)

End point values	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9619	9601		
Units: Participants	152	191		

## Statistical analyses

Statistical analysis title	Prevention of ischaemic stroke
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Statistical analysis description:

Time from randomisation to first occurrence of ischaemic stroke

Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
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Number of subjects included in analysis	19220
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Analysis specification	Pre-specified
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Analysis type	superiority
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P-value	= 0.0375 [4]
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Method	Regression, Cox
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Parameter estimate	Hazard ratio (HR)
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Point estimate	0.8
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Confidence interval

level	95 %
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sides	2-sided
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lower limit	0.64
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upper limit	0.99
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Notes:

[4] - The hypothesis will be tested at the 4.96% two-sided significance level to account for the planned interim analysis with the overall type I error preserved at 5%. A hierarchical test sequence will be used to address the issue of multiple testing

## Secondary: Prevention of all-cause death. The efficacy variable is time from randomisation to death of any cause

End point title	Prevention of all-cause death. The efficacy variable is time from randomisation to death of any cause
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End point description:

Participants with all-cause death. If no event, censoring occurs at the earliest of PACD and last endpoint assessment date. Includes deaths based on publically available vital status data in patients who have withdrawn consent.

End point type	Secondary
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End point timeframe:

From randomisation to primary analysis censoring date.

<b>End point values</b>	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9619	9601		
Units: Participants	579	592		

## Statistical analyses

<b>Statistical analysis title</b>	Prevention of all-cause death
Statistical analysis description:	
Time from randomisation to death of any cause	
Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
Number of subjects included in analysis	19220
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6846
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.87
upper limit	1.1

## Other pre-specified: Time to first TIMI Major bleeding event (primary safety objective)

End point title	Time to first TIMI Major bleeding event (primary safety objective)
End point description:	
Participants with TIMI major bleeding event. If no event, censoring occurs at the earliest of last endpoint assessment date, death date and 7 days following the date of last dose of study medication	
End point type	Other pre-specified
End point timeframe:	
From randomisation to 7 days following the date of last dose of study medication	

<b>End point values</b>	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9562 <sup>[5]</sup>	9531 <sup>[6]</sup>		
Units: Participants	206	100		

Notes:

[5] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

[6] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

### Statistical analyses

<b>Statistical analysis title</b>	TIMI major bleeding
Statistical analysis description:	
Time to first TIMI major bleeding event	
Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
Number of subjects included in analysis	19093
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	2.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.82
upper limit	2.94

### Other pre-specified: Time to first TIMI major or minor bleeding event

<b>End point title</b>	Time to first TIMI major or minor bleeding event
End point description:	
Participants with TIMI major or minor bleeding event. If no event, censoring occurs at the earliest of last endpoint assessment date, death date and 7 days following the date of last dose of study medication	
End point type	Other pre-specified
End point timeframe:	
From randomisation to 7 days following the date of last dose of study medication	

<b>End point values</b>	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9562 <sup>[7]</sup>	9531 <sup>[8]</sup>		
Units: Participants	285	129		

Notes:

[7] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

[8] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

### Statistical analyses

<b>Statistical analysis title</b>	TIMI major or minor bleeding
Statistical analysis description:	
Time to first TIMI major or minor bleeding	
Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
Number of subjects included in analysis	19093
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	2.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.02
upper limit	3.07

### Other pre-specified: Time to first PLATO major bleeding event

End point title	Time to first PLATO major bleeding event
End point description:	
Participants with PLATO major bleeding event. If no event, censoring occurs at the earliest of last endpoint assessment date, death date and 7 days following the date of last dose of study medication	
End point type	Other pre-specified
End point timeframe:	
From randomisation to 7 days following the date of last dose of study medication	

<b>End point values</b>	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9562 <sup>[9]</sup>	9531 <sup>[10]</sup>		
Units: Participants	310	145		

Notes:

[9] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

[10] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

### Statistical analyses

<b>Statistical analysis title</b>	PLATO major bleeding
Statistical analysis description:	
Time to first PLATO major bleeding	
Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo

Number of subjects included in analysis	19093
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	2.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.98
upper limit	2.93

### Other pre-specified: Time to first permanent discontinuation of study medication due to any bleeding event

End point title	Time to first permanent discontinuation of study medication due to any bleeding event
End point description:	
Participants with permanent discontinuation of study medication due to any bleeding event. If no event, censoring occurs at the earliest of last endpoint assessment date, death date and the date of last dose of study medication	
End point type	Other pre-specified
End point timeframe:	
From randomisation to 7 days following the date of last dose of study medication	

End point values	Ticagrelor 60 mg	Ticagrelor placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9562 <sup>[11]</sup>	9531 <sup>[12]</sup>		
Units: Participants	466	125		

Notes:

[11] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

[12] - Safety analyses included subjects who received at least 1 dose of randomised ticagrelor or placebo

### Statistical analyses

Statistical analysis title	Permanent discontinuation of IP due to bleeding
Statistical analysis description:	
Time to permanent discontinuation of study medication due to any bleeding event	
Comparison groups	Ticagrelor 60 mg v Ticagrelor placebo
Number of subjects included in analysis	19093
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	4.04

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Confidence interval	
level	95 %
sides	2-sided
lower limit	3.32
upper limit	4.92

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From Randomisation until last dose of study drug + 7 days

Adverse event reporting additional description:

Systematic assessment of suspected bleeding events, suspected endpoint events, serious adverse events, adverse events that leads to permanent discontinuation of study medication and non-serious AEs of interest (ie, dyspnoea, renal impairment, bradyarrhythmia, gout, and pneumonia),

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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### Reporting groups

Reporting group title	Ticagrelor
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Reporting group description: -

Reporting group title	Placebo
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Reporting group description: -

<b>Serious adverse events</b>	Ticagrelor	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	3049 / 9562 (31.89%)	3210 / 9531 (33.68%)	
number of deaths (all causes)	187	223	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 2	
Acute promyelocytic leukaemia			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma gastric		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma of colon		
subjects affected / exposed	14 / 9562 (0.15%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 14	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Adenocarcinoma pancreas		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Adrenal adenoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Adrenal neoplasm		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Anal cancer		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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 / 9562 (0.01%)	0 / 9531 (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	5 / 9562 (0.05%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	1 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Benign gastric neoplasm		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign neoplasm of thyroid gland		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Benign ovarian tumour		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Bladder cancer		
subjects affected / exposed	8 / 9562 (0.08%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 1
Bladder cancer recurrent		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neoplasm		

subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bone cancer metastatic</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bladder transitional cell carcinoma</b>		
subjects affected / exposed	2 / 9562 (0.02%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	1 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bowen's disease</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain neoplasm</b>		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Brain neoplasm malignant</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cancer female</b>		
subjects affected / exposed	9 / 9562 (0.09%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 0
<b>Breast neoplasm</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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 metastatic</b>		
subjects affected / exposed	1 / 9562 (0.01%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Bronchial carcinoma</b>		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Carcinoid tumour</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cerebellopontine angle tumour</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cervix carcinoma recurrent</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Cholangiocarcinoma</b>		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
<b>Cervix carcinoma stage 0</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cholesteatoma</b>		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chordoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Clear cell renal cell carcinoma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colon adenoma		
subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Colon cancer		
subjects affected / exposed	12 / 9562 (0.13%)	16 / 9531 (0.17%)
occurrences causally related to treatment / all	0 / 12	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0
Colon cancer metastatic		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 2
Colon neoplasm		

subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal adenocarcinoma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Colorectal cancer		
subjects affected / exposed	0 / 9562 (0.00%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cutaneous lymphoma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial adenocarcinoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer metastatic		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibroadenoma of breast		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrosarcoma		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fibrous histiocytoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder adenoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder cancer		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder neoplasm		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Gastric adenoma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric cancer		
subjects affected / exposed	7 / 9562 (0.07%)	10 / 9531 (0.10%)
occurrences causally related to treatment / all	1 / 7	1 / 10
deaths causally related to treatment / all	1 / 1	0 / 3
Gastric neoplasm		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal carcinoma</b>			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal lymphoma</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal melanoma</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Gastrointestinal neoplasm</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Gastrointestinal stromal tumour</b>			
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Gastrointestinal tract adenoma</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Glioblastoma</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Hepatic cancer</b>			

subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 2
Hepatic cancer metastatic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatobiliary neoplasm		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatocellular carcinoma		
subjects affected / exposed	9 / 9562 (0.09%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3
Invasive breast carcinoma		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Invasive ductal breast carcinoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine benign neoplasm		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal cancer		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Laryngeal neoplasm		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lentigo maligna		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Leukaemia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Lip and/or oral cavity cancer		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lip neoplasm malignant stage unspecified		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lipofibroma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lipoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung adenocarcinoma		
subjects affected / exposed	3 / 9562 (0.03%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Lung cancer metastatic		

subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Lung neoplasm		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung neoplasm malignant		
subjects affected / exposed	14 / 9562 (0.15%)	20 / 9531 (0.21%)
occurrences causally related to treatment / all	0 / 14	1 / 20
deaths causally related to treatment / all	0 / 8	0 / 12
Lymphoma		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant melanoma		
subjects affected / exposed	7 / 9562 (0.07%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant neoplasm of renal pelvis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 unknown primary site		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Meningioma benign		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to bone</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to central nervous system</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Metastases to liver</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Metastases to lung</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to peritoneum</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastases to pleura</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Metastatic gastric cancer</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Metastatic malignant melanoma</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Metastatic neoplasm</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Monoclonal gammopathy</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Muscle neoplasm</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal cancer</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myelodysplastic syndrome</b>		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Nasopharyngeal cancer</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neoplasm</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neoplasm malignant</b>		

subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Neoplasm prostate		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal adenocarcinoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	0 / 9562 (0.00%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Oesophageal neoplasm		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oral neoplasm benign		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		

subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Ovarian fibroma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian granulosa cell tumour		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian neoplasm		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	12 / 9562 (0.13%)	12 / 9531 (0.13%)
occurrences causally related to treatment / all	1 / 13	1 / 12
deaths causally related to treatment / all	0 / 8	1 / 7
Pancreatic carcinoma metastatic		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1
Pancreatic neoplasm		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Pancreatic neuroendocrine tumour		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic sarcoma		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Papillary cystadenoma lymphomatosum		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	0 / 9562 (0.00%)	1 / 9531 (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	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Penis carcinoma metastatic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Phyllodes tumour		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		

subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Plasmacytoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleomorphic liposarcoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural neoplasm		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
Prostate cancer		
subjects affected / exposed	31 / 9562 (0.32%)	36 / 9531 (0.38%)
occurrences causally related to treatment / all	0 / 31	0 / 36
deaths causally related to treatment / all	0 / 1	0 / 0
Prostate cancer metastatic		
subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3
Prostate cancer recurrent		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Prostate cancer stage 0		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic adenoma		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal adenocarcinoma		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer		
subjects affected / exposed	9 / 9562 (0.09%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	1 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal cancer recurrent		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal neoplasm		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectosigmoid cancer metastatic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	3 / 9562 (0.03%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 3	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer metastatic		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Renal cell carcinoma		
subjects affected / exposed	5 / 9562 (0.05%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Renal neoplasm		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Retroperitoneal cancer		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland adenoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland neoplasm		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin cancer		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer recurrent		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small cell lung cancer		

subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 2	0 / 1	
Small intestine adenocarcinoma			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestine carcinoma			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue sarcoma			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Squamous cell carcinoma of lung			
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the cervix			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 the oral cavity			

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Squamous cell carcinoma of the tongue		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid adenoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid cancer		
subjects affected / exposed	0 / 9562 (0.00%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Thyroid cancer recurrent		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thyroid neoplasm		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsil cancer		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell cancer of the renal pelvis and ureter		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	4 / 9562 (0.04%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tumour haemorrhage		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine cancer		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine leiomyoma		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval cancer		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
B-cell lymphoma stage I		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder transitional cell carcinoma stage II		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial cancer stage I		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endometrial cancer stage II			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant neoplasm papilla of Vater			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	3 / 9562 (0.03%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage III			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Air embolism			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiopathy			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			

subjects affected / exposed	8 / 9562 (0.08%)	9 / 9531 (0.09%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic arteriosclerosis</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic dissection</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Aortic stenosis</b>			
subjects affected / exposed	5 / 9562 (0.05%)	7 / 9531 (0.07%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arterial occlusive disease</b>			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arterial stenosis</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arterial thrombosis</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arteriosclerosis</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Artery dissection</b>			

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Atherosclerotic plaque rupture		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure inadequately controlled		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	1 / 9562 (0.01%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Deep vein thrombosis		
subjects affected / exposed	6 / 9562 (0.06%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic vascular disorder		
subjects affected / exposed	1 / 9562 (0.01%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism arterial		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolism venous		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extremity necrosis		

subjects affected / exposed	5 / 9562 (0.05%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	36 / 9562 (0.38%)	45 / 9531 (0.47%)
occurrences causally related to treatment / all	0 / 40	0 / 45
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	15 / 9562 (0.16%)	23 / 9531 (0.24%)
occurrences causally related to treatment / all	0 / 17	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	4 / 9562 (0.04%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension		
subjects affected / exposed	9 / 9562 (0.09%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 10	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery disease		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iliac artery embolism		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intermittent claudication		

subjects affected / exposed	9 / 9562 (0.09%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Labile blood pressure		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphocele		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphoedema		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Malignant hypertension		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrosis ischaemic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neurogenic shock		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	7 / 9562 (0.07%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		

subjects affected / exposed	31 / 9562 (0.32%)	48 / 9531 (0.50%)
occurrences causally related to treatment / all	0 / 38	0 / 60
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery aneurysm		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis		
subjects affected / exposed	10 / 9562 (0.10%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery thrombosis		
subjects affected / exposed	5 / 9562 (0.05%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral coldness		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	14 / 9562 (0.15%)	18 / 9531 (0.19%)
occurrences causally related to treatment / all	0 / 17	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder		

subjects affected / exposed	3 / 9562 (0.03%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral venous disease		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid vasculitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shock		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Shock haemorrhagic		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subclavian artery stenosis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subgaleal haematoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thrombophlebitis		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (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	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicose vein			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular compression			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular occlusion			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Administration site phlebitis			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			

subjects affected / exposed	4 / 9562 (0.04%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Capsular contracture associated with breast implant		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac death		
subjects affected / exposed	4 / 9562 (0.04%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 4	0 / 1
Catheter site haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest discomfort		
subjects affected / exposed	5 / 9562 (0.05%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chest pain		
subjects affected / exposed	6 / 9562 (0.06%)	11 / 9531 (0.12%)
occurrences causally related to treatment / all	1 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Complication associated with device		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Death		
subjects affected / exposed	52 / 9562 (0.54%)	60 / 9531 (0.63%)
occurrences causally related to treatment / all	0 / 52	1 / 60
deaths causally related to treatment / all	0 / 52	1 / 60
Drowning		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Facial pain		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fatigue		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body reaction		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gait disturbance		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gait inability		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General physical health deterioration		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Impaired healing		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Medical device site haemorrhage		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mucosal exfoliation		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Multiple organ dysfunction syndrome		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0
Necrobiosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Necrosis		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Nodule		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-cardiac chest pain		
subjects affected / exposed	54 / 9562 (0.56%)	66 / 9531 (0.69%)
occurrences causally related to treatment / all	0 / 60	0 / 72
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oedema peripheral		

subjects affected / exposed	1 / 9562 (0.01%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pacemaker generated arrhythmia</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Peripheral swelling</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyrexia</b>		
subjects affected / exposed	8 / 9562 (0.08%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 8	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sudden cardiac death</b>		
subjects affected / exposed	6 / 9562 (0.06%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	1 / 6	0 / 8
deaths causally related to treatment / all	1 / 6	0 / 8
<b>Sudden death</b>		
subjects affected / exposed	5 / 9562 (0.05%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 5	0 / 5
<b>Ulcer haemorrhage</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Vascular stent occlusion</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	6 / 9562 (0.06%)	4 / 9531 (0.04%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic reaction			
subjects affected / exposed	0 / 9562 (0.00%)	4 / 9531 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaphylactic shock			
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contrast media allergy			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug hypersensitivity			
subjects affected / exposed	0 / 9562 (0.00%)	4 / 9531 (0.04%)	
occurrences causally related to treatment / all	0 / 0	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sarcoidosis			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transplant rejection			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Acquired hydrocele			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acquired phimosis			
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign prostatic hyperplasia			
subjects affected / exposed	26 / 9562 (0.27%)	21 / 9531 (0.22%)	
occurrences causally related to treatment / all	1 / 26	0 / 21	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast mass			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix disorder			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			

subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial atrophy		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial hyperplasia		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Genital haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gynaecomastia		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postmenopausal haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic fibrosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic haemorrhage		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic obstruction		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatism		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis		
subjects affected / exposed	7 / 9562 (0.07%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	2 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatomegaly		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine fibrosis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine polyp		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Uterine prolapse		

subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal prolapse			
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	6 / 9562 (0.06%)	7 / 9531 (0.07%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 1	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Aspiration			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute respiratory failure			
subjects affected / exposed	11 / 9562 (0.12%)	7 / 9531 (0.07%)	
occurrences causally related to treatment / all	0 / 12	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 2	
Asthma			
subjects affected / exposed	14 / 9562 (0.15%)	7 / 9531 (0.07%)	
occurrences causally related to treatment / all	1 / 18	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthmatic crisis			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial obstruction		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchial disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis chronic		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchospasm		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Choking		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic obstructive pulmonary disease		
subjects affected / exposed	27 / 9562 (0.28%)	41 / 9531 (0.43%)
occurrences causally related to treatment / all	0 / 41	3 / 57
deaths causally related to treatment / all	0 / 0	0 / 1
Chronic respiratory failure		

subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic paralysis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	35 / 9562 (0.37%)	29 / 9531 (0.30%)
occurrences causally related to treatment / all	9 / 36	4 / 29
deaths causally related to treatment / all	0 / 0	0 / 1
Dyspnoea exertional		
subjects affected / exposed	5 / 9562 (0.05%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 5	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysema		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottic cyst		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epistaxis		
subjects affected / exposed	20 / 9562 (0.21%)	11 / 9531 (0.12%)
occurrences causally related to treatment / all	16 / 20	9 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Haemoptysis		
subjects affected / exposed	4 / 9562 (0.04%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	2 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Haemothorax		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrothorax		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic interstitial pneumonia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Idiopathic pulmonary fibrosis		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Interstitial lung disease		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 1
Laryngeal oedema		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung disorder		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infiltration		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal haemorrhage		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal polyps		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal septum deviation		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Obstructive airways disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Organising pneumonia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orthopnoea		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paranasal cyst		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pleural effusion		
subjects affected / exposed	1 / 9562 (0.01%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pleurisy		

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumonia aspiration</b>		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Pneumonitis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pneumothorax spontaneous</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary arterial hypertension</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary congestion</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pulmonary embolism</b>		
subjects affected / exposed	16 / 9562 (0.17%)	19 / 9531 (0.20%)
occurrences causally related to treatment / all	0 / 16	1 / 19
deaths causally related to treatment / all	0 / 3	0 / 1
<b>Pulmonary fibrosis</b>		

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertension			
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary mass			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	10 / 9562 (0.10%)	5 / 9531 (0.05%)	
occurrences causally related to treatment / all	0 / 10	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary sarcoidosis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary toxicity			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory alkalosis			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory arrest			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory disorder			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Respiratory failure</b>			
subjects affected / exposed	8 / 9562 (0.08%)	8 / 9531 (0.08%)	
occurrences causally related to treatment / all	0 / 9	0 / 8	
deaths causally related to treatment / all	0 / 2	0 / 2	
<b>Restrictive pulmonary disease</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sinus congestion</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Sleep apnoea syndrome</b>			
subjects affected / exposed	4 / 9562 (0.04%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Psychiatric disorders</b>			
<b>Adjustment disorder</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Affective disorder</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Anxiety</b>			
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Bipolar disorder</b>			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Borderline personality disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Completed suicide		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Confusional state		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Delirium tremens		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Depression		
subjects affected / exposed	6 / 9562 (0.06%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Depression suicidal		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disorientation		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Illness anxiety disorder			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental disorder			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropsychiatric symptoms			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device failure			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device loosening			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	1 / 9562 (0.01%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Device occlusion			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile output decreased			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood follicle stimulating hormone increased			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose fluctuation			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood glucose increased		
subjects affected / exposed	5 / 9562 (0.05%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blood lactic acid increased		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Blood potassium increased		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Blood pressure increased		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Blood urine present		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac stress test abnormal		
subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Electrocardiogram abnormal		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glycosylated haemoglobin increased		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemoglobin decreased</b>		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	1 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Heart rate irregular</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hepatic enzyme increased</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Occult blood positive</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oxygen saturation decreased</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Prostatic specific antigen increased</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Troponin increased</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Weight decreased</b>		

subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count decreased			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram QRS complex prolonged			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrocardiogram ST segment depression			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis B surface antigen positive			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accident at home			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Adrenal gland injury			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia postoperative			
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic leak			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anastomotic stenosis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	8 / 9562 (0.08%)	8 / 9531 (0.08%)	
occurrences causally related to treatment / all	0 / 8	1 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial bypass thrombosis			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod bite			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Avulsion fracture			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Burns third degree		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Carbon monoxide poisoning		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Carotid artery restenosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cataract traumatic		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical vertebral fracture		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clavicle fracture		
subjects affected / exposed	1 / 9562 (0.01%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Concussion		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Contusion		

subjects affected / exposed	7 / 9562 (0.07%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary artery restenosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary vascular graft occlusion		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coronary vascular graft stenosis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	5 / 9562 (0.05%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Dislocation of sternum		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epidural haemorrhage		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Extraskkeletal ossification		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Facial bones fracture		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Failure to anastomose		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	5 / 9562 (0.05%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	8 / 9562 (0.08%)	15 / 9531 (0.16%)
occurrences causally related to treatment / all	0 / 8	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Fibula fracture		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Foot fracture		

subjects affected / exposed	2 / 9562 (0.02%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Foreign body in gastrointestinal tract		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fracture		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fractured sacrum		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hand fracture		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Heat stroke		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Head injury		
subjects affected / exposed	8 / 9562 (0.08%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Hip fracture		
subjects affected / exposed	8 / 9562 (0.08%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Humerus fracture		

subjects affected / exposed	12 / 9562 (0.13%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 12	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Incisional hernia		
subjects affected / exposed	1 / 9562 (0.01%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hyphaema		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc injury		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Joint injury		
subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	1 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament injury		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament rupture		
subjects affected / exposed	4 / 9562 (0.04%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ligament sprain		

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Limb injury</b>		
subjects affected / exposed	12 / 9562 (0.13%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 13	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lower limb fracture</b>		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbar vertebral fracture</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lumbosacral plexus injury</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Median nerve injury</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Meniscus injury</b>		
subjects affected / exposed	9 / 9562 (0.09%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple fractures</b>		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Multiple injuries</b>		

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle injury		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle strain		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nail injury		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve injury		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve root injury		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nerve root injury lumbar		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Overdose		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Patella fracture		

subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvic fracture		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periprocedural myocardial infarction		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Post procedural complication		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural fever		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haematoma		
subjects affected / exposed	4 / 9562 (0.04%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural haemorrhage		
subjects affected / exposed	11 / 9562 (0.12%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	6 / 11	4 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative ileus		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative respiratory failure		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative thoracic procedure complication		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural complication		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (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	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	1 / 2	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Procedural pain		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pubis fracture		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary contusion		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radiation pneumonitis		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radius fracture		
subjects affected / exposed	6 / 9562 (0.06%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Rib fracture		
subjects affected / exposed	4 / 9562 (0.04%)	10 / 9531 (0.10%)
occurrences causally related to treatment / all	0 / 4	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Scapula fracture		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Seroma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Shunt malfunction		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skeletal injury		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin abrasion		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin injury		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin laceration		
subjects affected / exposed	2 / 9562 (0.02%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal column injury		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	0 / 9562 (0.00%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord injury cervical		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sternal fracture		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stomal hernia		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subdural haematoma		
subjects affected / exposed	23 / 9562 (0.24%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	12 / 23	3 / 6
deaths causally related to treatment / all	0 / 2	0 / 0
Subcutaneous haematoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	8 / 9562 (0.08%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	3 / 8	3 / 5
deaths causally related to treatment / all	0 / 0	2 / 2
Tendon injury		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	2 / 9562 (0.02%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Thermal burn		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Thoracic vertebral fracture		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tibia fracture		
subjects affected / exposed	3 / 9562 (0.03%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Toxicity to various agents		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic fracture		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haematoma		
subjects affected / exposed	7 / 9562 (0.07%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	4 / 7	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic haemorrhage		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Traumatic haemothorax		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Traumatic intracranial haemorrhage		

subjects affected / exposed	11 / 9562 (0.12%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	4 / 11	1 / 7
deaths causally related to treatment / all	1 / 2	0 / 0
Ulna fracture		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Upper limb fracture		
subjects affected / exposed	6 / 9562 (0.06%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary retention postoperative		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft complication		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular graft thrombosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular pseudoaneurysm		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound dehiscence		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Wound haemorrhage</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Wound necrosis</b>			
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Wrist fracture</b>			
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Congenital, familial and genetic disorders</b>			
<b>Corneal dystrophy</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Glucose-6-phosphate dehydrogenase deficiency</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Neurofibromatosis</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Cardiac disorders</b>			
<b>Acute coronary syndrome</b>			
subjects affected / exposed	20 / 9562 (0.21%)	22 / 9531 (0.23%)	
occurrences causally related to treatment / all	3 / 20	1 / 22	
deaths causally related to treatment / all	0 / 1	0 / 2	

Acute left ventricular failure subjects affected / exposed	5 / 9562 (0.05%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Acute myocardial infarction subjects affected / exposed	126 / 9562 (1.32%)	197 / 9531 (2.07%)
occurrences causally related to treatment / all	6 / 133	7 / 203
deaths causally related to treatment / all	0 / 14	0 / 19
Angina pectoris subjects affected / exposed	200 / 9562 (2.09%)	251 / 9531 (2.63%)
occurrences causally related to treatment / all	5 / 239	7 / 267
deaths causally related to treatment / all	0 / 0	0 / 0
Angina unstable subjects affected / exposed	354 / 9562 (3.70%)	405 / 9531 (4.25%)
occurrences causally related to treatment / all	13 / 403	16 / 449
deaths causally related to treatment / all	0 / 0	1 / 1
Aortic valve disease subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve stenosis subjects affected / exposed	8 / 9562 (0.08%)	14 / 9531 (0.15%)
occurrences causally related to treatment / all	0 / 8	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Arteriosclerosis coronary artery		

subjects affected / exposed	9 / 9562 (0.09%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Atrial fibrillation</b>		
subjects affected / exposed	82 / 9562 (0.86%)	76 / 9531 (0.80%)
occurrences causally related to treatment / all	0 / 84	3 / 80
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial flutter</b>		
subjects affected / exposed	12 / 9562 (0.13%)	13 / 9531 (0.14%)
occurrences causally related to treatment / all	0 / 13	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial tachycardia</b>		
subjects affected / exposed	2 / 9562 (0.02%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrial thrombosis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block</b>		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block complete</b>		
subjects affected / exposed	16 / 9562 (0.17%)	18 / 9531 (0.19%)
occurrences causally related to treatment / all	3 / 16	2 / 18
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block first degree</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Atrioventricular block second degree</b>		

subjects affected / exposed	12 / 9562 (0.13%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	1 / 12	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Bifascicular block		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	15 / 9562 (0.16%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	2 / 15	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (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	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac arrest		
subjects affected / exposed	7 / 9562 (0.07%)	12 / 9531 (0.13%)
occurrences causally related to treatment / all	1 / 7	1 / 12
deaths causally related to treatment / all	1 / 6	1 / 9
Cardiac disorder		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac failure		

subjects affected / exposed	64 / 9562 (0.67%)	87 / 9531 (0.91%)
occurrences causally related to treatment / all	2 / 84	0 / 108
deaths causally related to treatment / all	0 / 11	0 / 9
Cardiac failure acute		
subjects affected / exposed	20 / 9562 (0.21%)	14 / 9531 (0.15%)
occurrences causally related to treatment / all	6 / 27	0 / 15
deaths causally related to treatment / all	0 / 4	0 / 4
Cardiac failure chronic		
subjects affected / exposed	18 / 9562 (0.19%)	30 / 9531 (0.31%)
occurrences causally related to treatment / all	0 / 19	1 / 44
deaths causally related to treatment / all	0 / 1	1 / 2
Cardiac failure congestive		
subjects affected / exposed	60 / 9562 (0.63%)	47 / 9531 (0.49%)
occurrences causally related to treatment / all	0 / 71	2 / 53
deaths causally related to treatment / all	0 / 4	0 / 3
Cardiac tamponade		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Cardiac valve disease		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac ventricular scarring		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardio-respiratory arrest		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 2
Cardiogenic shock		

subjects affected / exposed	6 / 9562 (0.06%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 4
<b>Cardiomyopathy</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cardiopulmonary failure</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Cardiovascular insufficiency</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Coronary artery disease</b>		
subjects affected / exposed	85 / 9562 (0.89%)	90 / 9531 (0.94%)
occurrences causally related to treatment / all	3 / 89	5 / 95
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Coronary artery occlusion</b>		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Coronary artery insufficiency</b>		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
<b>Coronary artery stenosis</b>		
subjects affected / exposed	14 / 9562 (0.15%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 14	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dressler's syndrome</b>		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive heart disease		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular dysfunction		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	7 / 9562 (0.07%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Microvascular coronary artery disease		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve stenosis		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial fibrosis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Myocardial infarction</b>		
subjects affected / exposed	41 / 9562 (0.43%)	65 / 9531 (0.68%)
occurrences causally related to treatment / all	0 / 43	1 / 66
deaths causally related to treatment / all	0 / 11	0 / 16
<b>Myocarditis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myocardial ischaemia</b>		
subjects affected / exposed	36 / 9562 (0.38%)	47 / 9531 (0.49%)
occurrences causally related to treatment / all	1 / 37	0 / 50
deaths causally related to treatment / all	0 / 0	0 / 2
<b>Nodal arrhythmia</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial effusion</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Palpitations</b>		
subjects affected / exposed	4 / 9562 (0.04%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pericardial haemorrhage</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pericarditis constrictive		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prinzmetal angina		
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary valve incompetence		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Right ventricular failure		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sinoatrial block		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus arrhythmia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus bradycardia		

subjects affected / exposed	7 / 9562 (0.07%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus node dysfunction		
subjects affected / exposed	5 / 9562 (0.05%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Sinus tachycardia		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress cardiomyopathy		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular extrasystoles		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Supraventricular tachycardia		
subjects affected / exposed	5 / 9562 (0.05%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	1 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Tachycardia		
subjects affected / exposed	1 / 9562 (0.01%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Tricuspid valve incompetence		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ventricular arrhythmia		

subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular asystole</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
<b>Ventricular extrasystoles</b>			
subjects affected / exposed	4 / 9562 (0.04%)	7 / 9531 (0.07%)	
occurrences causally related to treatment / all	0 / 4	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ventricular fibrillation</b>			
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 1	0 / 0	
<b>Ventricular tachycardia</b>			
subjects affected / exposed	10 / 9562 (0.10%)	6 / 9531 (0.06%)	
occurrences causally related to treatment / all	1 / 10	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Adams-Stokes syndrome</b>			
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Nervous system disorders</b>			
<b>Altered state of consciousness</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Ageusia</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Amnesia</b>			

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ataxia</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Balance disorder</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Basal ganglia haemorrhage</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Basal ganglia infarction</b>		
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain hypoxia</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Brain injury</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 haemorrhage</b>		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0
deaths causally related to treatment / all	2 / 3	0 / 0
<b>Brain stem infarction</b>		

subjects affected / exposed	1 / 9562 (0.01%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain stem stroke</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid arteriosclerosis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery disease</b>		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery occlusion</b>		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid artery stenosis</b>		
subjects affected / exposed	18 / 9562 (0.19%)	21 / 9531 (0.22%)
occurrences causally related to treatment / all	0 / 18	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carotid sinus syndrome</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Carpal tunnel syndrome</b>		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Cauda equina syndrome</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar haemorrhage		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar infarction		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebellar stroke		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral arteriosclerosis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral atrophy		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haematoma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral haemorrhage		
subjects affected / exposed	6 / 9562 (0.06%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	3 / 6	3 / 6
deaths causally related to treatment / all	1 / 2	2 / 4
Cerebral infarction		

subjects affected / exposed	18 / 9562 (0.19%)	27 / 9531 (0.28%)
occurrences causally related to treatment / all	2 / 19	2 / 28
deaths causally related to treatment / all	0 / 2	0 / 3
Cerebral ischaemia		
subjects affected / exposed	7 / 9562 (0.07%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral small vessel ischaemic disease		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	3 / 9562 (0.03%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	0 / 3	1 / 9
deaths causally related to treatment / all	0 / 1	0 / 1
Cerebrovascular insufficiency		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical cord compression		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical radiculopathy		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cervicobrachial syndrome		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cluster headache		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cognitive disorder		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Coma		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Dementia		
subjects affected / exposed	2 / 9562 (0.02%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1
Diabetic coma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic neuropathy		
subjects affected / exposed	9 / 9562 (0.09%)	13 / 9531 (0.14%)
occurrences causally related to treatment / all	0 / 10	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Dizziness		
subjects affected / exposed	14 / 9562 (0.15%)	12 / 9531 (0.13%)
occurrences causally related to treatment / all	1 / 15	2 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Dysarthria		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic cerebral infarction		

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Embolitic stroke			
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Epilepsy			
subjects affected / exposed	1 / 9562 (0.01%)	5 / 9531 (0.05%)	
occurrences causally related to treatment / all	0 / 2	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Encephalopathy			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epileptic encephalopathy			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential tremor			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	1 / 9562 (0.01%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal dyscognitive seizures			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage intracranial		
subjects affected / exposed	1 / 9562 (0.01%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	1 / 1	2 / 4
deaths causally related to treatment / all	1 / 1	0 / 1
Haemorrhagic transformation stroke		
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhagic stroke		
subjects affected / exposed	10 / 9562 (0.10%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	7 / 10	6 / 9
deaths causally related to treatment / all	3 / 3	1 / 2
Headache		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hemianopia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic encephalopathy		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hemiparesis		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydrocephalus		

subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoaesthesia		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive encephalopathy		
subjects affected / exposed	5 / 9562 (0.05%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic coma		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic seizure		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic encephalopathy		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemic unconsciousness		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial aneurysm		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intracranial pressure increased		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cerebral infarction		
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic stroke		
subjects affected / exposed	85 / 9562 (0.89%)	119 / 9531 (1.25%)
occurrences causally related to treatment / all	1 / 88	0 / 127
deaths causally related to treatment / all	0 / 8	0 / 5
Lacunar infarction		
subjects affected / exposed	9 / 9562 (0.09%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 10	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Lacunar stroke		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	4 / 9562 (0.04%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar radiculopathy		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbosacral radiculopathy		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Microsleep		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 / 9562 (0.01%)	1 / 9531 (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	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelopathy		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	1 / 9562 (0.01%)	0 / 9531 (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 / 9562 (0.01%)	1 / 9531 (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 / 9562 (0.00%)	1 / 9531 (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 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Paralysis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinson's disease		
subjects affected / exposed	1 / 9562 (0.01%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Parkinsonism		
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral nerve lesion		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Petit mal epilepsy		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polyneuropathy		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Post-traumatic headache		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Presyncope		

subjects affected / exposed	5 / 9562 (0.05%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudoradicular syndrome		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Putamen haemorrhage		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Radicular pain		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Radiculopathy		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Sciatica		
subjects affected / exposed	4 / 9562 (0.04%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Sedation		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Seizure		
subjects affected / exposed	2 / 9562 (0.02%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal cord compression		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal epidural haematoma		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Subarachnoid haemorrhage		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	1 / 2	3 / 3
deaths causally related to treatment / all	0 / 0	1 / 1
Syncope		
subjects affected / exposed	26 / 9562 (0.27%)	27 / 9531 (0.28%)
occurrences causally related to treatment / all	0 / 29	1 / 28
deaths causally related to treatment / all	0 / 0	0 / 0
Tension headache		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamic infarction		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thalamus haemorrhage		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Thoracic outlet syndrome		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Toxic encephalopathy		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient global amnesia		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	39 / 9562 (0.41%)	33 / 9531 (0.35%)
occurrences causally related to treatment / all	3 / 39	1 / 34
deaths causally related to treatment / all	0 / 0	0 / 0
Tremor		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular dementia		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Vascular encephalopathy		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery dissection		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery stenosis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency		

subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia with Lewy bodies			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
IIIrd nerve paralysis			
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Miller Fisher syndrome			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve disorder			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paralysis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIth nerve paresis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertigo CNS origin			
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Abdominal lymphadenopathy			

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Agranulocytosis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anaemia</b>		
subjects affected / exposed	20 / 9562 (0.21%)	14 / 9531 (0.15%)
occurrences causally related to treatment / all	13 / 20	3 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anaemia macrocytic</b>		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anaemia of chronic disease</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anaemia of malignant disease</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Deficiency anaemia</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Disseminated intravascular coagulation</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhagic anaemia</b>		

subjects affected / exposed	10 / 9562 (0.10%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	7 / 10	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypochromic anaemia		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Immune thrombocytopenic purpura		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Increased tendency to bruise		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Iron deficiency anaemia		
subjects affected / exposed	26 / 9562 (0.27%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	13 / 26	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Leukocytosis		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lymphadenopathy		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Microcytic anaemia		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrogenic anaemia		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neutropenia</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Normochromic normocytic anaemia</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Normocytic anaemia</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancytopenia</b>		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Splenic infarction</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spontaneous haematoma</b>		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	3 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spontaneous haemorrhage</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Thrombocytopenia</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness neurosensory			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deafness unilateral			
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear pain			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eustachian tube dysfunction			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoacusis			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inner ear disorder			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Meniere's disease		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Sudden hearing loss		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tinnitus		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tympanic membrane perforation		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tympanosclerosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo		
subjects affected / exposed	13 / 9562 (0.14%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 13	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Vestibular disorder		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Vertigo positional		

subjects affected / exposed	7 / 9562 (0.07%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 7	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Eye disorders</b>			
Age-related macular degeneration			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aphakia			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	22 / 9562 (0.23%)	30 / 9531 (0.31%)	
occurrences causally related to treatment / all	0 / 26	1 / 35	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract cortical			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract diabetic			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract nuclear			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal degeneration			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			

subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Entropion		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eye haemorrhage		
subjects affected / exposed	4 / 9562 (0.04%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	3 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Eyelid ptosis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glaucoma		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lacrimal disorder		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular degeneration		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular fibrosis		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Macular oedema		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Macular pseudohole		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Maculopathy		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Open angle glaucoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Optic ischaemic neuropathy		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery occlusion		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal artery thrombosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal degeneration		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Retinal detachment		

subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal haemorrhage</b>		
subjects affected / exposed	2 / 9562 (0.02%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	2 / 2	3 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal vein occlusion</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinal vein thrombosis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinopathy</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Retinopathy proliferative</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rhegmatogenous retinal detachment</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Strabismus</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative keratitis			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	9 / 9562 (0.09%)	5 / 9531 (0.05%)	
occurrences causally related to treatment / all	5 / 9	2 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous opacities			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal discomfort			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			

subjects affected / exposed	7 / 9562 (0.07%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain lower		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal pain upper		
subjects affected / exposed	1 / 9562 (0.01%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fissure		
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Abdominal wall haematoma		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis noninfective		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Anal inflammation		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendix disorder		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ascites		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bezoar		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Change of bowel habit		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	2 / 9562 (0.02%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic gastrointestinal bleeding		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Coeliac disease		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Colitis ischaemic		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Colitis		
subjects affected / exposed	4 / 9562 (0.04%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 4	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Constipation		
subjects affected / exposed	4 / 9562 (0.04%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dental caries		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gastroparesis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diaphragmatic hernia		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	18 / 9562 (0.19%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	1 / 18	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticular perforation		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Diverticulitis oesophageal		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal		
subjects affected / exposed	4 / 9562 (0.04%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	1 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic		
subjects affected / exposed	5 / 9562 (0.05%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	4 / 6	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal polyp		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer		
subjects affected / exposed	4 / 9562 (0.04%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	2 / 4	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenal ulcer haemorrhage		
subjects affected / exposed	7 / 9562 (0.07%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	7 / 8	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Duodenitis		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dyspepsia</b>		
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Dysphagia</b>		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Enteritis</b>		
subjects affected / exposed	2 / 9562 (0.02%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Enterocolitis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Epigastric discomfort</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erosive oesophagitis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Faecaloma</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Faeces discoloured</b>		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Food poisoning		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Functional gastrointestinal disorder		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric antral vascular ectasia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric haemorrhage		
subjects affected / exposed	6 / 9562 (0.06%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	5 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric polyps		
subjects affected / exposed	5 / 9562 (0.05%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer		
subjects affected / exposed	18 / 9562 (0.19%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	8 / 18	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer haemorrhage		

subjects affected / exposed	6 / 9562 (0.06%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	2 / 6	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastric ulcer perforation		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis		
subjects affected / exposed	8 / 9562 (0.08%)	12 / 9531 (0.13%)
occurrences causally related to treatment / all	2 / 8	2 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis erosive		
subjects affected / exposed	9 / 9562 (0.09%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	4 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	6 / 9562 (0.06%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	3 / 6	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroduodenal ulcer		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		

subjects affected / exposed	43 / 9562 (0.45%)	22 / 9531 (0.23%)
occurrences causally related to treatment / all	30 / 44	18 / 23
deaths causally related to treatment / all	0 / 1	0 / 0
Gastrointestinal inflammation		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ischaemia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal motility disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal polyp haemorrhage		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal stenosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	2 / 3	2 / 2
deaths causally related to treatment / all	1 / 1	0 / 0
Gastrooesophageal reflux disease		
subjects affected / exposed	5 / 9562 (0.05%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 6	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Haematemesis		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haematochezia</b>		
subjects affected / exposed	4 / 9562 (0.04%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	3 / 4	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhagic erosive gastritis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhoidal haemorrhage</b>		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Haemorrhoids</b>		
subjects affected / exposed	5 / 9562 (0.05%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 5	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hernial eventration</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus</b>		
subjects affected / exposed	4 / 9562 (0.04%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hiatus hernia</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ileus paralytic</b>		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Incarcerated inguinal hernia		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal hernia		
subjects affected / exposed	16 / 9562 (0.17%)	20 / 9531 (0.21%)
occurrences causally related to treatment / all	0 / 16	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal haemorrhage		
subjects affected / exposed	6 / 9562 (0.06%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	4 / 6	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal ischaemia		
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 2
Intestinal perforation		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal obstruction		
subjects affected / exposed	4 / 9562 (0.04%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal polyp		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal pseudo-obstruction		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal strangulation		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestinal haemorrhage		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine perforation		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Large intestine polyp		
subjects affected / exposed	18 / 9562 (0.19%)	14 / 9531 (0.15%)
occurrences causally related to treatment / all	1 / 18	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Lower gastrointestinal haemorrhage		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	3 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar hernia		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Mechanical ileus		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Melaena		

subjects affected / exposed	12 / 9562 (0.13%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	5 / 12	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Nausea</b>		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Obstruction gastric</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Obstructive pancreatitis</b>		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal motility disorder</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal spasm</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal ulcer</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophageal ulcer haemorrhage</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Oesophagitis</b>		

subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophagitis ulcerative		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic mass		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatic pseudocyst		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis		
subjects affected / exposed	11 / 9562 (0.12%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 14	0 / 7
deaths causally related to treatment / all	0 / 2	0 / 1
Pancreatitis acute		
subjects affected / exposed	2 / 9562 (0.02%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatitis chronic		
subjects affected / exposed	4 / 9562 (0.04%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pancreatolithiasis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peptic ulcer haemorrhage		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontal disease		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal adhesions		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritoneal haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Proctitis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal haemorrhage		
subjects affected / exposed	13 / 9562 (0.14%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	11 / 13	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal polyp		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal prolapse		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reflux gastritis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal haemorrhage		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Salivary gland calculus		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Small intestinal obstruction		
subjects affected / exposed	3 / 9562 (0.03%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Subileus		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth disorder		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Swollen tongue		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth socket haemorrhage		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcerative gastritis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia			
subjects affected / exposed	4 / 9562 (0.04%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Umbilical hernia, obstructive			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	22 / 9562 (0.23%)	10 / 9531 (0.10%)	
occurrences causally related to treatment / all	17 / 23	7 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			

subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bile duct obstruction		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0
Bile duct stone		
subjects affected / exposed	7 / 9562 (0.07%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary colic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Biliary dyskinesia		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis		
subjects affected / exposed	1 / 9562 (0.01%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1
Cholangitis acute		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis chronic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	13 / 9562 (0.14%)	23 / 9531 (0.24%)
occurrences causally related to treatment / all	0 / 14	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis acute		
subjects affected / exposed	19 / 9562 (0.20%)	14 / 9531 (0.15%)
occurrences causally related to treatment / all	0 / 19	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis chronic		
subjects affected / exposed	5 / 9562 (0.05%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1
Cholelithiasis		
subjects affected / exposed	23 / 9562 (0.24%)	25 / 9531 (0.26%)
occurrences causally related to treatment / all	0 / 24	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Cholestasis		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cirrhosis alcoholic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Drug-induced liver injury		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gallbladder disorder		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic cirrhosis		
subjects affected / exposed	4 / 9562 (0.04%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1
Hepatic failure		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatic function abnormal		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis acute		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Jaundice cholestatic		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Liver injury		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein thrombosis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steatohepatitis			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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			
Actinic elastosis			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angioedema			
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decubitus ulcer			
subjects affected / exposed	0 / 9562 (0.00%)	3 / 9531 (0.03%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermal cyst			
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis			

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	29 / 9562 (0.30%)	18 / 9531 (0.19%)
occurrences causally related to treatment / all	0 / 32	0 / 25
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ulcer		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ecchymosis		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intertrigo		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic skin ulcer		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Lichen planus		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myxoid cyst		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Necrobiosis lipoidica diabetorum		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Petechiae		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Prurigo		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin exfoliation		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin mass		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	7 / 9562 (0.07%)	12 / 9531 (0.13%)	
occurrences causally related to treatment / all	0 / 7	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic skin eruption			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	3 / 9562 (0.03%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	56 / 9562 (0.59%)	39 / 9531 (0.41%)	
occurrences causally related to treatment / all	2 / 59	2 / 43	
deaths causally related to treatment / all	0 / 1	0 / 1	
Azotaemia			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction			

subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder neck sclerosis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder outlet obstruction		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Bladder tamponade		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus bladder		
subjects affected / exposed	3 / 9562 (0.03%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Calculus urethral		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	6 / 9562 (0.06%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	1 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic kidney disease		
subjects affected / exposed	9 / 9562 (0.09%)	15 / 9531 (0.16%)
occurrences causally related to treatment / all	0 / 10	0 / 15
deaths causally related to treatment / all	0 / 1	0 / 0
Cystitis haemorrhagic		

subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic nephropathy		
subjects affected / exposed	6 / 9562 (0.06%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Dysuria		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
End stage renal disease		
subjects affected / exposed	4 / 9562 (0.04%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0
Glomerulonephritis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Glomerulosclerosis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematuria		
subjects affected / exposed	32 / 9562 (0.33%)	13 / 9531 (0.14%)
occurrences causally related to treatment / all	16 / 33	8 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
Haemorrhage urinary tract		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hydronephrosis		

subjects affected / exposed	4 / 9562 (0.04%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive nephropathy		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Micturition disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephritic syndrome		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrolithiasis		
subjects affected / exposed	16 / 9562 (0.17%)	21 / 9531 (0.22%)
occurrences causally related to treatment / all	1 / 19	1 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Nephropathy toxic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Nephrotic syndrome		
subjects affected / exposed	1 / 9562 (0.01%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Pelvi-ureteric obstruction		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Perinephritis		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Proteinuria		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery arteriosclerosis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery occlusion		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal artery stenosis		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal colic		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cyst		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal failure		

subjects affected / exposed	16 / 9562 (0.17%)	15 / 9531 (0.16%)
occurrences causally related to treatment / all	2 / 17	2 / 15
deaths causally related to treatment / all	0 / 0	0 / 1
Renal haemorrhage		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal hypertension		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Renal impairment		
subjects affected / exposed	10 / 9562 (0.10%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Renal injury		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal mass		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Stress urinary incontinence		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tubulointerstitial nephritis		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteric stenosis		

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	18 / 9562 (0.19%)	13 / 9531 (0.14%)	
occurrences causally related to treatment / all	1 / 20	0 / 14	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral haemorrhage			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral stenosis			
subjects affected / exposed	5 / 9562 (0.05%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary bladder polyp			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	4 / 9562 (0.04%)	7 / 9531 (0.07%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Goitre</b>			
subjects affected / exposed	5 / 9562 (0.05%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperparathyroidism</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperparathyroidism primary</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hyperthyroidism</b>			
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Hypothyroidism</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Thyroiditis subacute</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Musculoskeletal and connective tissue disorders</b>			
<b>Arthralgia</b>			
subjects affected / exposed	5 / 9562 (0.05%)	6 / 9531 (0.06%)	
occurrences causally related to treatment / all	0 / 5	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Arthritis</b>			

subjects affected / exposed	4 / 9562 (0.04%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis reactive		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Arthropathy		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Back pain		
subjects affected / exposed	10 / 9562 (0.10%)	14 / 9531 (0.15%)
occurrences causally related to treatment / all	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
Bone pain		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis		
subjects affected / exposed	0 / 9562 (0.00%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Cervical spinal stenosis		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chest wall mass		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chondromalacia		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Compartment syndrome		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Costochondritis		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Crystal arthropathy		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic amyotrophy		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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	0 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Facial asymmetry		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fistula		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Flank pain		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Foot deformity		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty arthritis		
subjects affected / exposed	4 / 9562 (0.04%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	1 / 4	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Gouty tophus		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Inguinal mass		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc degeneration		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc disorder		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc protrusion		
subjects affected / exposed	16 / 9562 (0.17%)	19 / 9531 (0.20%)
occurrences causally related to treatment / all	0 / 17	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 0
Intervertebral disc space narrowing		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint contracture		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Joint swelling		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Loose body in joint		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lumbar spinal stenosis		
subjects affected / exposed	13 / 9562 (0.14%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 13	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Meniscal degeneration		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscle disorder		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Muscular weakness		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal chest pain		

subjects affected / exposed	9 / 9562 (0.09%)	15 / 9531 (0.16%)
occurrences causally related to treatment / all	0 / 9	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Musculoskeletal pain</b>		
subjects affected / exposed	2 / 9562 (0.02%)	9 / 9531 (0.09%)
occurrences causally related to treatment / all	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myalgia</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myofascitis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myopathy</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Myositis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neck pain</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Neuropathic arthropathy</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoarthritis</b>		

subjects affected / exposed	47 / 9562 (0.49%)	55 / 9531 (0.58%)
occurrences causally related to treatment / all	1 / 51	1 / 57
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteochondrosis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteonecrosis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteopenia</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoporosis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteoporotic fracture</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteorrhagia</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pain in extremity</b>		
subjects affected / exposed	4 / 9562 (0.04%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Patellofemoral pain syndrome</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pathological fracture		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periarthritis		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Polymyalgia rheumatica		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriatic arthropathy		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pseudarthrosis		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Rhabdomyolysis		
subjects affected / exposed	6 / 9562 (0.06%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Rheumatoid arthritis		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sacroiliitis		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rotator cuff syndrome</b>		
subjects affected / exposed	5 / 9562 (0.05%)	8 / 9531 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scoliosis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Seronegative arthritis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Soft tissue disorder</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal column stenosis</b>		
subjects affected / exposed	8 / 9562 (0.08%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal ligament ossification</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Spinal osteoarthritis</b>		

subjects affected / exposed	6 / 9562 (0.06%)	11 / 9531 (0.12%)	
occurrences causally related to treatment / all	0 / 6	0 / 12	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spinal pain</b>			
subjects affected / exposed	5 / 9562 (0.05%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spondylitis</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Spondylolisthesis</b>			
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Synovial cyst</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tendon disorder</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Tenosynovitis stenosans</b>			
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Infections and infestations</b>			
<b>Abdominal abscess</b>			
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Abdominal sepsis</b>			

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abdominal wall abscess</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess jaw</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess limb</b>		
subjects affected / exposed	5 / 9562 (0.05%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Abscess neck</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Acinetobacter infection</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Acute endocarditis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
<b>Acute sinusitis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Anal abscess</b>		

subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Anal fistula infection		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendiceal abscess		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis		
subjects affected / exposed	13 / 9562 (0.14%)	10 / 9531 (0.10%)
occurrences causally related to treatment / all	0 / 14	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0
Appendicitis perforated		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arthritis infective		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atypical pneumonia		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacteraemia		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bacterial diarrhoea		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bacterial sepsis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Biliary sepsis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Brain abscess</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast abscess</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Breast cellulitis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchiolitis</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis</b>		
subjects affected / exposed	18 / 9562 (0.19%)	22 / 9531 (0.23%)
occurrences causally related to treatment / all	0 / 18	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Bronchitis bacterial</b>		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bursitis infective		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Campylobacter gastroenteritis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis		
subjects affected / exposed	35 / 9562 (0.37%)	45 / 9531 (0.47%)
occurrences causally related to treatment / all	0 / 40	0 / 51
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis gangrenous		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis of male external genital organ		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangitis infective		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholecystitis infective		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic sinusitis		

subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile colitis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Clostridium difficile infection		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Complicated appendicitis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cystitis		
subjects affected / exposed	4 / 9562 (0.04%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Dacryocystitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue fever		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Dengue haemorrhagic fever		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Device related infection		

subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Device related sepsis		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (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	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis		
subjects affected / exposed	11 / 9562 (0.12%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	1 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Ear infection		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Dysentery		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Emphysematous cystitis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Endocarditis		
subjects affected / exposed	0 / 9562 (0.00%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 0	1 / 5
deaths causally related to treatment / all	0 / 0	1 / 2
Endophthalmitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
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	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enterobacter pneumonia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Enterocolitis infectious		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epididymitis		
subjects affected / exposed	4 / 9562 (0.04%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Epiglottitis		

subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Erysipelas</b>		
subjects affected / exposed	12 / 9562 (0.13%)	10 / 9531 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Eye infection viral</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Escherichia urinary tract infection</b>		
subjects affected / exposed	2 / 9562 (0.02%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Febrile infection</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Fungal infection</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gangrene</b>		
subjects affected / exposed	5 / 9562 (0.05%)	12 / 9531 (0.13%)
occurrences causally related to treatment / all	0 / 5	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis</b>		
subjects affected / exposed	14 / 9562 (0.15%)	18 / 9531 (0.19%)
occurrences causally related to treatment / all	1 / 15	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Gastroenteritis bacterial</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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 / 9562 (0.00%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal infection		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Genitourinary tract infection		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Graft infection		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Groin abscess		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Helicobacter gastritis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes ophthalmic		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes virus infection		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Herpes zoster		
subjects affected / exposed	5 / 9562 (0.05%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Incision site abscess		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected bite		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected cyst		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Infected skin ulcer		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (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 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious colitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infectious pleural effusion		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of bronchiectasis		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Influenza		
subjects affected / exposed	8 / 9562 (0.08%)	10 / 9531 (0.10%)
occurrences causally related to treatment / all	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 0
Joint abscess		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Kidney infection		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (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	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	7 / 9562 (0.07%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	4 / 9562 (0.04%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ludwig angina		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lung abscess		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	10 / 9562 (0.10%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 12	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0
Meningitis		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Meningitis bacterial		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Meningococcal infection		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Necrotising fasciitis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Neutropenic sepsis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal candidiasis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ophthalmic herpes zoster		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	5 / 9562 (0.05%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Osteomyelitis		

subjects affected / exposed	14 / 9562 (0.15%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 16	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis acute</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Osteomyelitis chronic</b>		
subjects affected / exposed	3 / 9562 (0.03%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media</b>		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media acute</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Otitis media chronic</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pancreas infection</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Papilloma viral infection</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Parainfluenzae virus infection</b>		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Parotitis		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Perineal abscess		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Periorbital cellulitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	3 / 9562 (0.03%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis bacterial		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonsillar abscess		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pharyngeal abscess		

subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumocystis jirovecii infection		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	130 / 9562 (1.36%)	147 / 9531 (1.54%)
occurrences causally related to treatment / all	1 / 137	4 / 153
deaths causally related to treatment / all	0 / 9	0 / 10
Pneumonia bacterial		
subjects affected / exposed	3 / 9562 (0.03%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia escherichia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia influenzal		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia mycoplasmal		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia staphylococcal		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Pneumonia streptococcal		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia viral		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural infection		
subjects affected / exposed	2 / 9562 (0.02%)	3 / 9531 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Post procedural sepsis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatic abscess		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	3 / 9562 (0.03%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis		
subjects affected / exposed	8 / 9562 (0.08%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Pyelonephritis acute		

subjects affected / exposed	3 / 9562 (0.03%)	12 / 9531 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Rectal abscess</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Pyelonephritis chronic</b>		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Respiratory tract infection</b>		
subjects affected / exposed	4 / 9562 (0.04%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Respiratory tract infection viral</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Salmonellosis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Scrotal abscess</b>		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Sepsis</b>		
subjects affected / exposed	14 / 9562 (0.15%)	20 / 9531 (0.21%)
occurrences causally related to treatment / all	0 / 15	0 / 20
deaths causally related to treatment / all	0 / 4	0 / 5
<b>Septic shock</b>		

subjects affected / exposed	7 / 9562 (0.07%)	7 / 9531 (0.07%)
occurrences causally related to treatment / all	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 3	0 / 2
Skin infection		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Sinusitis		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Soft tissue infection		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal sepsis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Staphylococcal infection		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal infection		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Streptococcal sepsis		
subjects affected / exposed	4 / 9562 (0.04%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Subcutaneous abscess		

subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tonsillitis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tooth abscess		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tracheobronchitis mycoplasmal		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Tuberculosis of genitourinary system		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Upper respiratory tract infection		
subjects affected / exposed	3 / 9562 (0.03%)	5 / 9531 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Ureteritis		

subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	33 / 9562 (0.35%)	36 / 9531 (0.38%)
occurrences causally related to treatment / all	2 / 37	1 / 50
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection bacterial		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Urosepsis		
subjects affected / exposed	12 / 9562 (0.13%)	10 / 9531 (0.10%)
occurrences causally related to treatment / all	0 / 13	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 3
Vestibular neuronitis		
subjects affected / exposed	1 / 9562 (0.01%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Viral infection		
subjects affected / exposed	2 / 9562 (0.02%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval abscess		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vulval cellulitis		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Wound infection		

subjects affected / exposed	5 / 9562 (0.05%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Acute hepatitis B		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic hepatitis C		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
H1N1 influenza		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis A		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis C		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hepatitis E		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostatitis Escherichia coli		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
West Nile viral infection		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Metabolism and nutrition disorders</b>			
<b>Decreased appetite</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Dehydration</b>			
subjects affected / exposed	6 / 9562 (0.06%)	5 / 9531 (0.05%)	
occurrences causally related to treatment / all	0 / 7	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetes mellitus</b>			
subjects affected / exposed	24 / 9562 (0.25%)	42 / 9531 (0.44%)	
occurrences causally related to treatment / all	0 / 28	0 / 46	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetes mellitus inadequate control</b>			
subjects affected / exposed	50 / 9562 (0.52%)	60 / 9531 (0.63%)	
occurrences causally related to treatment / all	0 / 55	0 / 78	
deaths causally related to treatment / all	0 / 0	0 / 1	
<b>Diabetic complication</b>			
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Diabetic ketoacidosis</b>			
subjects affected / exposed	10 / 9562 (0.10%)	11 / 9531 (0.12%)	
occurrences causally related to treatment / all	0 / 11	0 / 13	
deaths causally related to treatment / all	0 / 2	0 / 0	
<b>Diabetic metabolic decompensation</b>			
subjects affected / exposed	9 / 9562 (0.09%)	17 / 9531 (0.18%)	
occurrences causally related to treatment / all	0 / 9	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Euglycaemic diabetic ketoacidosis</b>			

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	5 / 9562 (0.05%)	6 / 9531 (0.06%)
occurrences causally related to treatment / all	1 / 7	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Hypercalcaemia		
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	20 / 9562 (0.21%)	22 / 9531 (0.23%)
occurrences causally related to treatment / all	0 / 21	0 / 24
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperkalaemia		
subjects affected / exposed	5 / 9562 (0.05%)	4 / 9531 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypoglycaemia		

subjects affected / exposed	33 / 9562 (0.35%)	25 / 9531 (0.26%)
occurrences causally related to treatment / all	0 / 39	0 / 26
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Hypokalaemia</b>		
subjects affected / exposed	2 / 9562 (0.02%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypomagnesaemia</b>		
subjects affected / exposed	1 / 9562 (0.01%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hyponatraemia</b>		
subjects affected / exposed	5 / 9562 (0.05%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypophosphataemia</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Hypovolaemia</b>		
subjects affected / exposed	0 / 9562 (0.00%)	2 / 9531 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Ketoacidosis</b>		
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
<b>Lactic acidosis</b>		
subjects affected / exposed	2 / 9562 (0.02%)	0 / 9531 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
<b>Metabolic acidosis</b>		

subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Obesity</b>			
subjects affected / exposed	1 / 9562 (0.01%)	0 / 9531 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Type 2 diabetes mellitus</b>			
subjects affected / exposed	12 / 9562 (0.13%)	19 / 9531 (0.20%)	
occurrences causally related to treatment / all	0 / 12	1 / 19	
deaths causally related to treatment / all	0 / 0	0 / 0	
<b>Vitamin D deficiency</b>			
subjects affected / exposed	0 / 9562 (0.00%)	1 / 9531 (0.01%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
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>	Ticagrelor	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1951 / 9562 (20.40%)	610 / 9531 (6.40%)	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>Dyspnoea</b>			
subjects affected / exposed	1951 / 9562 (20.40%)	610 / 9531 (6.40%)	
occurrences (all)	2479	687	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 May 2015	Ticagrelor dose changed from 90 mg bd to 60 mg bd. Changes in secondary objectives From: The secondary objectives of the study (presented in hierarchical order) are to compare the effect of long-term treatment with ticagrelor versus placebo for 1 Prevention of the composite of all-cause death, MI or stroke. 2 Prevention of CV death. 3 Prevention of all-cause death. To: The secondary objectives of the study (presented in hierarchical order) are to compare the effect of long-term treatment with ticagrelor versus placebo for 1 Prevention of CV death. 2 Prevention of MI. 3 Prevention of ischaemic stroke. 4 Prevention of all-cause death.
23 September 2015	An increase in number of patients to be enrolled in the study, and a change in the anticipated length of the study
07 February 2017	A change in the anticipated length of the study to increase the number of primary endpoint events collected. Inclusion of collection of concomitant medications at study closure visit.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

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

Overall 19271 patients were randomised to study drug, of which 51 patients were randomised to study drug at a site prematurely closed by sponsor and these patients were excluded from the study results.

Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/30788847>

<http://www.ncbi.nlm.nih.gov/pubmed/31475798>

<http://www.ncbi.nlm.nih.gov/pubmed/31484629>