Clinical trial results:
A randomized controlled trial of rivaroxaban for the prevention of major cardiovascular events in patients with coronary or peripheral artery disease (COMPASS - Cardiovascular OutcoMes for People using Anticoagulation StrategieS)

Summary

EudraCT number	2012-004180-43
Trial protocol	IE SE CZ FI IT HU NL GB SK DK BE
Global end of trial date	15 June 2021

Results information

Result version number	v1 (current)
This version publication date	01 June 2022
First version publication date	01 June 2022

Trial information

Trial identification

Sponsor protocol code	15786

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01776424
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser-Wilhelm-Allee, Leverkusen, Germany, D-51368
Public contact	Therapeutic Area Head, Bayer AG, +49 30 300139003, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, +49 30 300139003, clinical-trials-contact@bayer.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	15 June 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 June 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Primary objectives for rivaroxaban randomization were to determine whether rivaroxaban 2.5 mg twice daily (bid)/ aspirin 100 mg once daily (od) compared with aspirin 100 mg od reduces the risk of a composite of myocardial infarction (MI), stroke, or cardiovascular (CV) death in subjects with coronary artery disease (CAD) or peripheral artery disease (PAD); and to determine whether rivaroxaban 5 mg bid compared with aspirin 100 mg od reduces the risk of a composite of MI, stroke or CV death in subjects with CAD or PAD.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki and the International Council for Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent was read by and explained to all the subjects. Participating subjects signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy:

Subjects not on continuous proton pump inhibitor (PPI) at randomization were additionally randomized to pantoprazole 40 mg, once daily or pantoprazole placebo.

Evidence for comparator: -

Actual start date of recruitment	28 February 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	14 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 2443
Country: Number of subjects enrolled	United States: 1475
Country: Number of subjects enrolled	Australia: 353
Country: Number of subjects enrolled	Belgium: 455
Country: Number of subjects enrolled	Switzerland: 58
Country: Number of subjects enrolled	Germany: 766
Country: Number of subjects enrolled	Denmark: 575
Country: Number of subjects enrolled	Finland: 119
Country: Number of subjects enrolled	France: 191
Country: Number of subjects enrolled	United Kingdom: 541
Country: Number of subjects enrolled	Ireland: 382

Country: Number of subjects enrolled	Israel: 263
Country: Number of subjects enrolled	Italy: 1014
Country: Number of subjects enrolled	Netherlands: 2522
Country: Number of subjects enrolled	Sweden: 735
Country: Number of subjects enrolled	South Africa: 581
Country: Number of subjects enrolled	Czechia: 1553
Country: Number of subjects enrolled	Hungary: 734
Country: Number of subjects enrolled	Poland: 518
Country: Number of subjects enrolled	Romania: 423
Country: Number of subjects enrolled	Russian Federation: 682
Country: Number of subjects enrolled	Slovakia: 92
Country: Number of subjects enrolled	Ukraine: 821
Country: Number of subjects enrolled	China: 1086
Country: Number of subjects enrolled	Japan: 1556
Country: Number of subjects enrolled	Korea, Republic of: 415
Country: Number of subjects enrolled	Malaysia: 247
Country: Number of subjects enrolled	Philippines: 651
Country: Number of subjects enrolled	Argentina: 2789
Country: Number of subjects enrolled	Brazil: 1515
Country: Number of subjects enrolled	Chile: 641
Country: Number of subjects enrolled	Colombia: 942
Country: Number of subjects enrolled	Ecuador: 257
Worldwide total number of subjects	27395
EEA total number of subjects	10079

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)	6517
From 65 to 84 years	20870
85 years and over	8

Subject disposition

Recruitment

Recruitment details:

Study was conducted at 608 centers with randomized subjects in 33 countries between 28 Feb 2013 (first patient first visit) and 15 Jun 2021 (last patient last visit of long-term open-label extension part).

Pre-assignment

Screening details:

Overall, 29872 subjects were screened, of which 2477 subjects were screen failures. A total of 27395 subjects were randomized to antithrombotic treatment. 17598 subjects were randomized to pantoprazole/placebo treatment. 12964 subjects joined long-term open-label extension (LTOLE) part.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Rivaroxaban 2.5mg + Aspirin 100mg

Arm description:

Subjects received rivaroxaban 2.5 mg twice daily (bid) and aspirin 100 mg once daily (od). All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a proton pump inhibitor (PPI), were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.

Arm type	Experimental
Investigational medicinal product name	Rivaroxaban
Investigational medicinal product code	BAY59-7939
Other name	Xarelto
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet, 2.5 mg, twice daily, oral

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

Dosage and administration details:

Tablet, 40 mg, once daily, oral, for subjects who were not on a PPI and who were randomized to pantoprazole

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

Dosage and administration details:

Pantoprazole matching placebo, once daily, oral, for subjects who were not on a PPI and who were randomized to pantoprazole placebo

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

Dosage and administration details:

Tablet, 100 mg, once daily, oral

Arm title	Rivaroxaban 5mg + Aspirin Placebo

Arm description:

Subjects received rivaroxaban 5 mg bid and aspirin placebo od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.

Arm type	Experimental
Investigational medicinal product name	Rivaroxaban
Investigational medicinal product code	BAY59-7939
Other name	Xarelto
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet, 5 mg, twice daily, oral

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

Dosage and administration details:

Aspirin matching placebo, once daily, oral

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

Dosage and administration details:

Tablet, 40 mg, once daily, oral, for subjects who were not on a PPI and who were randomized to pantoprazole

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

Dosage and administration details:

Pantoprazole matching placebo, once daily, oral, for subjects who were not on a PPI and who were randomized to pantoprazole placebo

Arm title	Rivaroxaban Placebo + Aspirin 100mg

Arm description:

Subjects received rivaroxaban placebo bid and aspirin 100 mg od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.

Arm type	Experimental

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

Dosage and administration details:

Rivaroxaban matching placebo, twice daily, oral

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

Dosage and administration details:

Pantoprazole matching placebo, once daily, oral, for subjects who were not on a PPI and who were randomized to pantoprazole placebo

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

Dosage and administration details:

Tablet, 40 mg, once daily, oral, for subjects who were not on a PPI and who were randomized to pantoprazole

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

Dosage and administration details:

Tablet, 100 mg, once daily, oral

Number of subjects in period 1	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo	Rivaroxaban Placebo + Aspirin 100mg
Started	9152	9117	9126
Treated with antithrombotic treatment	9134	9109	9107
Randomized to study pantoprazole/placebo	5878 [1]	5859 [2]	5861 [3]
Completed	9132	9098	9102
Not completed	20	19	24
Consent withdrawn by subject	10	11	15
Lost to follow-up	10	8	9

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Subjects under antithrombotic treatment who did not have a continuous need to take a proton pump inhibitor (PPI), were additionally randomized 1:1 to receive pantoprazole or matching placebo.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Subjects under antithrombotic treatment who did not have a continuous need to take a proton pump inhibitor (PPI), were additionally randomized 1:1 to receive pantoprazole or matching placebo.
[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Subjects under antithrombotic treatment who did not have a continuous need to take a proton pump inhibitor (PPI), were additionally randomized 1:1 to receive pantoprazole or matching placebo.

Period 2

Period 2 title	LTOLE part (open label)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	LTOLE part: Rivaroxaban 2.5mg + Aspirin 100mg

Arm description:

Subjects who consented to LTOLE part received open label rivaroxaban 2.5 mg bid and aspirin 100 mg od in LTOLE part.

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

Dosage and administration details:

Tablet, 100 mg, once daily, oral

Investigational medicinal product name	Rivaroxaban
Investigational medicinal product code	BAY59-7939
Other name	Xarelto
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet, 2.5 mg, twice daily, oral

Number of subjects in period 2[4]	LTOLE part: Rivaroxaban 2.5mg + Aspirin 100mg
Started	12964
Treated in LTOLE part	12903
Completed	12745
Not completed	219
Missing final visit	188
Lost to follow-up	13
Refused	18

Notes:

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

Justification: Subjects from antithrombotic study part who gave their written informed consent to participate in the LTOLE part and who met the eligibility criteria were included in the LTOLE study part.

Baseline characteristics

Reporting groups	
Reporting group title	Rivaroxaban 2.5mg + Aspirin 100mg
Reporting group description:	
Subjects received rivaroxaban 2.5 mg twice daily (bid) and aspirin 100 mg once daily (od). All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a proton pump inhibitor (PPI), were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.	
Reporting group title	Rivaroxaban 5mg + Aspirin Placebo
Reporting group description:	
Subjects received rivaroxaban 5 mg bid and aspirin placebo od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.	
Reporting group title	Rivaroxaban Placebo + Aspirin 100mg
Reporting group description:	
Subjects received rivaroxaban placebo bid and aspirin 100 mg od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.	

Reporting group values	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo	Rivaroxaban Placebo + Aspirin 100mg
Number of subjects	9152	9117	9126
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	68.3	68.2	68.2
standard deviation	± 7.9	± 7.9	± 8.0
Gender Categorical Units: Subjects			
Female	2059	1972	1989
Male	7093	7145	7137
Race/Ethnicity Units: Subjects			
Chinese	388	381	376
Hispanic	1769	1751	1758
White/Caucasian	5673	5672	5682
South Asian	107	102	106
Other Asian	956	938	915
Black/African American	76	94	92
Other	183	179	197

Reporting group values	Total		
Number of subjects	27395		
Age Categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	- 		
Gender Categorical Units: Subjects			
Female	6020		
Male	21375		
Race/Ethnicity Units: Subjects			
Chinese	1145		
Hispanic	5278		
White/Caucasian	17027		
South Asian	315		
Other Asian	2809		
Black/African American	262		
Other	559		

End points

End points reporting groups

Reporting group title	Rivaroxaban 2.5mg + Aspirin 100mg

Reporting group description:

Subjects received rivaroxaban 2.5 mg twice daily (bid) and aspirin 100 mg once daily (od). All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a proton pump inhibitor (PPI), were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.

Reporting group title	Rivaroxaban 5mg + Aspirin Placebo

Reporting group description:

Subjects received rivaroxaban 5 mg bid and aspirin placebo od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.

Reporting group title	Rivaroxaban Placebo + Aspirin 100mg

Reporting group description:

Subjects received rivaroxaban placebo bid and aspirin 100 mg od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od.

Reporting group title	LTOLE part: Rivaroxaban 2.5mg + Aspirin 100mg

Reporting group description:

Subjects who consented to LTOLE part received open label rivaroxaban 2.5 mg bid and aspirin 100 mg od in LTOLE part.

Subject analysis set title	Intent-to-treatment Analysis Set (ITT)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

ITT included all subjects randomized to antithrombotic treatment for the initial study part. The ITT set comprised both subjects randomized to pantoprazole/placebo and subjects not randomized to pantoprazole/placebo.

Subject analysis set title	LTOLE Intent-to-treat Analysis Set (LTOLE ITT)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

LTOLE ITT included all subjects who completed COMPASS LTOLE initiation visit (LTOLE initiation visit date entered).

Subject analysis set title	LTOLE Safety Analysis Set (LTOLE SAF)
Subject analysis set type	Safety analysis

Subject analysis set description:

LTOLE SAF: included all subjects who completed COMPASS LTOLE initiation visit and who received at least one dose of medication in LTOLE part.

Primary: The first occurrence of the composite primary efficacy outcome, myocardial infarction (MI), stroke, or cardiovascular (CV) death

End point title	The first occurrence of the composite primary efficacy outcome, myocardial infarction (MI), stroke, or cardiovascular (CV) death

End point description:

Count of subjects and time from randomization to the first occurrence of the composite primary efficacy outcome, MI, stroke, or CV death were evaluated. Hazard ratios were calculated and reported as statistical analysis.

End point type	Primary

End point timeframe:

For each subject, the first occurrence of the composite primary efficacy outcome after randomization up until the global rivaroxaban/aspirin outcomes cut-off date (06 FEB 2017) was considered. The mean time in follow-up until that date was 702 days.

End point values	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo	Rivaroxaban Placebo + Aspirin 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9152[1]	9117[2]	9126[3]	
Units: Subjects	379	448	496	

Notes:

[1] - ITT

[2] - ITT

[3] - ITT

Statistical analyses

Statistical analysis title	Time to first composite primary efficacy outcome

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 2.5mg + Aspirin 100mg v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.00004 [4]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.86

Notes:

[4] - Independent DSMB recommended to stop rivaroxaban/aspirin arms on 06FEB2017. At first interim analysis(~50% events) the log-rank test statistic for one primary comparison had crossed the modified Haybittle-Peto boundary(z=4) consistently over 3 months

Statistical analysis title	Time to first composite primary efficacy outcome

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 5mg + Aspirin Placebo v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18243
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1149
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.03

Primary: The first occurrence of the primary safety outcome major bleeding based on a modification of the International Society on Thrombosis and Haemostasis (ISTH) criteria

End point title	The first occurrence of the primary safety outcome major bleeding based on a modification of the International Society on Thrombosis and Haemostasis (ISTH) criteria

End point description:

Modified ISTH major bleeding is defined as: i) Fatal bleeding, or ii) Symptomatic bleeding in a critical area or organ, such as intraarticular, intracranial, intramuscular with compartment syndrome, intraocular, intraspinal, liver, pancreas, pericardial, respiratory, retroperitoneal, adrenal gland or kidney; or bleeding into the surgical site requiring reoperation, or iii) Bleeding leading to hospitalization (major bleeding also includes presentation to an acute care facility with discharge on the same day). Count of subjects and time from randomization to the first occurrence of the primary safety outcome major bleeding were evaluated. Hazard ratios were calculated and reported as statistical analysis.

End point type	Primary

End point timeframe:

For each subject, the first occurrence of modified ISTH major bleeding after randomization up until the global rivaroxaban/aspirin outcomes cut-off date (06 FEB 2017) was considered. The mean time in follow-up until that date was 702 days.

End point values	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo	Rivaroxaban Placebo + Aspirin 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9152[5]	9117[6]	9126[7]	
Units: Subjects	288	255	170	

Notes:

[5] - ITT

[6] - ITT

[7] - ITT

Statistical analyses

Statistical analysis title	Time to first primary safety outcome

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 2.5mg + Aspirin 100mg v Rivaroxaban Placebo + Aspirin 100mg

Number of subjects included in analysis	18278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.00001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	2.05

Statistical analysis title	Time to first primary safety outcome

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and Stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 5mg + Aspirin Placebo v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18243
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.00003
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	1.84

Secondary: The first occurrence of myocardial infarction (MI), ischemic stroke, acute limb ischemia (ALI), or coronary heart disease (CHD) death

End point title	The first occurrence of myocardial infarction (MI), ischemic stroke, acute limb ischemia (ALI), or coronary heart disease (CHD) death

End point description:

Count of participants and time from randomization to the first occurrence of MI, ischemic stroke, ALI, or CHD death were evaluated. Hazard ratios were calculated and reported as statistical analysis.

End point type	Secondary

End point timeframe:

For each subject, the first occurrence of MI, ischemic stroke, ALI, or CHD death after randomization up until the global rivaroxaban/aspirin outcomes cut-off date (06 FEB 2017) was considered. The mean time in follow-up until that date was 702 days.

End point values	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo	Rivaroxaban Placebo + Aspirin 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9152	9117	9126	
Units: Subjects	329	397	450	

Statistical analyses

Statistical analysis title	Time to first MI, ischemic stroke,ALI or CHD death
Statistical analysis description:	
Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.	
Comparison groups	Rivaroxaban 2.5mg + Aspirin 100mg v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.00001 [8]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.83

Notes:

[8] - Nominal p-value

Statistical analysis title	Time to first MI, ischemic stroke,ALI or CHD death
Statistical analysis description:	
Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.	
Comparison groups	Rivaroxaban 5mg + Aspirin Placebo v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18243
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.06437
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.01

Notes:

[9] - Nominal p-value

Secondary: The first occurrence of MI, ischemic stroke, ALI, or cardiovascular (CV) death

End point title	The first occurrence of MI, ischemic stroke, ALI, or cardiovascular (CV) death

End point description:

Count of subjects and time from randomization to the first occurrence of MI, ischemic stroke, ALI, or CV death were evaluated. Hazard ratios were calculated and reported as statistical analysis.

End point type	Secondary

End point timeframe:

For each subject, the first occurrence of MI, ischemic stroke, ALI, or CV death after randomization up until the global rivaroxaban/aspirin outcomes cut-off date (06 FEB 2017) was considered. The mean time in follow-up until that date was 702 days.

End point values	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo	Rivaroxaban Placebo + Aspirin 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9152[10]	9117[11]	9126[12]	
Units: Subjects	389	453	516	

Notes:

[10] - ITT

[11] - ITT

[12] - ITT

Statistical analyses

Statistical analysis title	Time to first MI, ischemic stroke, ALI or CV death

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 2.5mg + Aspirin 100mg v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.00001 [13]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.85

Notes:

[13] - Nominal p-value

Statistical analysis title	Time to first MI, ischemic stroke, ALI or CV death

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 5mg + Aspirin Placebo v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18243
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.03995 [14]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.99

Notes:

[14] - Nominal p-value

Secondary: All-cause mortality

End point title	All-cause mortality

End point description:

Count of subjects and time from randomization to death by all cause were evaluated. Hazard ratios were calculated and reported as statistical analysis.

End point type	Secondary

End point timeframe:

For each subjects, death by any cause after randomization up until the global rivaroxaban/aspirin outcomes cut-off date (06 FEB 2017) was considered. The mean time in follow-up until that date was 702 days.

End point values	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo	Rivaroxaban Placebo + Aspirin 100mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9152[15]	9117[16]	9126[17]	
Units: Subjects	313	366	378	

Notes:

[15] - ITT

[16] - ITT

[17] - ITT

Statistical analyses

Statistical analysis title	Time to death by all cause

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 2.5mg + Aspirin 100mg v Rivaroxaban Placebo + Aspirin 100mg

Number of subjects included in analysis	18278
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.01062 [18]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.96

Notes:

[18] - Nominal p-value

Statistical analysis title	Time to death by all cause

Statistical analysis description:

Log-rank test stratified by pantoprazole randomization and stratified Cox proportional hazards model were used in the analyses.

Comparison groups	Rivaroxaban 5mg + Aspirin Placebo v Rivaroxaban Placebo + Aspirin 100mg
Number of subjects included in analysis	18243
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.66418 [19]
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.12

Notes:

[19] - Nominal p-value

Other pre-specified: The first occurrence of the primary safety outcome major bleeding based on a modification of the International Society on Thrombosis and Haemostasis (ISTH) criteria in LTOLE part

End point title	The first occurrence of the primary safety outcome major bleeding based on a modification of the International Society on Thrombosis and Haemostasis (ISTH) criteria in LTOLE part

End point description:

Modified ISTH major bleeding is defined as: i) Fatal bleeding, or ii) Symptomatic bleeding in a critical area or organ, such as intraarticular, intracranial, intramuscular with compartment syndrome, intraocular, intraspinal, liver, pancreas, pericardial, respiratory, retroperitoneal, adrenal gland or kidney; or bleeding into the surgical site requiring reoperation, or iii) Bleeding leading to hospitalization (major bleeding also includes presentation to an acute care facility with discharge on the same day). Count of subjects from COMPASS LTOLE initiation visit to the first occurrence of the primary safety outcome major bleeding was evaluated.

End point type	Other pre-specified

End point timeframe:

For each subject, the first occurrence of modified ISTH major bleeding from COMPASS LTOLE initiation visit up until 2 days after the last treatment in LTOLE part was considered. The mean time in follow-up

was 421 days.

End point values	LTOLE part: Rivaroxaban 2.5mg + Aspirin 100mg			
Subject group type	Reporting group			
Number of subjects analysed	12903[20]			
Units: Subjects	138			

Notes:

[20] - LTOLE SAF

Statistical analyses

No statistical analyses for this end point

Other pre-specified: All-cause mortality in LTOLE part

End point title	All-cause mortality in LTOLE part

End point description:

Count of subjects from COMPASS LTOLE initiation visit to death by all cause were evaluated.

End point type	Other pre-specified

End point timeframe:

For each subjects, death by any cause after COMPASS LTOLE initiation visit up until the the last LTOLE part contact date was considered. The mean time in follow-up until that date was 428 days.

End point values	LTOLE part: Rivaroxaban 2.5mg + Aspirin 100mg			
Subject group type	Reporting group			
Number of subjects analysed	12964[21]			
Units: Subjects	282			

Notes:

[21] - LTOLE ITT

Statistical analyses

No statistical analyses for this end point

Other pre-specified: The first occurrence of the composite primary efficacy outcome, myocardial infarction (MI), stroke, or cardiovascular (CV) death in LTOLE part

End point title	The first occurrence of the composite primary efficacy outcome, myocardial infarction (MI), stroke, or cardiovascular (CV) death in LTOLE part

End point description:

Count of subjects from COMPASS LTOLE initiation visit to the first occurrence of the composite primary efficacy outcome, MI, stroke, or CV death were evaluated.

End point type	Other pre-specified

End point timeframe:

For each subject, the first occurrence of the composite primary efficacy outcome after from COMPASS LTOLE initiation visit up until last LTOLE part contact date was considered. The mean time in follow-up was 428 days.

End point values	LTOLE part: Rivaroxaban 2.5mg + Aspirin 100mg			
Subject group type	Reporting group			
Number of subjects analysed	12964[22]			
Units: Subjects	353			

Notes:

[22] - LTOLE ITT

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From randomization up to 2 days following permanent discontinuation of any antithrombotic study treatment, with an average duration of about 3 years (including a mean duration of 478 days between end of antithrombotic study part and start of LTOLE part)

Adverse event reporting additional description:

All-Cause Mortality reporting in the AE section encompasses all death cases in the entire safety analysis set (SAF) before the last contact visit, with an average duration of about 3 years. Two subjects who received treatment in LTOLE part but were never treated in antithrombotic study, therefore the entire SAF comprised 27352 subjects.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Rivaroxaban 2.5mg + Aspirin 100mg

Reporting group description:

Subjects received rivaroxaban 2.5 mg twice daily (bid) and aspirin 100 mg once daily (od). All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a proton pump inhibitor (PPI), were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od. Subjects who consented to LTOLE part received open label rivaroxaban 2.5 mg bid and aspirin 100 mg od in LTOLE part.

Reporting group title	Rivaroxaban Placebo + Aspirin 100mg

Reporting group description:

Subjects received rivaroxaban placebo bid and aspirin 100 mg od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od. Subjects who consented to LTOLE part received open label rivaroxaban 2.5 mg bid and aspirin 100 mg od in LTOLE part.

Reporting group title	Rivaroxaban 5mg + Aspirin Placebo

Reporting group description:

Subjects received rivaroxaban 5 mg bid and aspirin placebo od. All doses were provided in tablet form for oral administration. Subjects who did not have a continuous need to take a PPI, were additionally randomized 1:1 to receive pantoprazole 40 mg (tablet form for oral administration, od) or matching placebo od. Subjects who consented to LTOLE part received open label rivaroxaban 2.5 mg bid and aspirin 100 mg od in LTOLE part.

Serious adverse events	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban Placebo + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	781 / 9135 (8.55%)	715 / 9108 (7.85%)	755 / 9109 (8.29%)
number of deaths (all causes)	631	657	653
number of deaths resulting from adverse events	185	181	166
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute myeloid leukaemia			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 0
Adenocarcinoma			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma gastric			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma of colon			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoma benign			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Basal cell carcinoma			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct cancer			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Biliary neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	3 / 9135 (0.03%)	8 / 9108 (0.09%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 6	0 / 0
Bladder cancer recurrent			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cancer			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm malignant			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Breast cancer			

subjects affected / exposed	7 / 9135 (0.08%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Cervix carcinoma			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholangiocarcinoma			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Colon cancer			
subjects affected / exposed	10 / 9135 (0.11%)	6 / 9108 (0.07%)	6 / 9109 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 6	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 1
Cholesteatoma			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse large B-cell lymphoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroma			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer stage IV			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gallbladder cancer			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastric cancer			
subjects affected / exposed	8 / 9135 (0.09%)	6 / 9108 (0.07%)	8 / 9109 (0.09%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 4	0 / 4	0 / 1
Gastrointestinal carcinoma			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemangioma of skin			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal cancer			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial tumour haemorrhage			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypopharyngeal cancer			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Laryngeal neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lipoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	1 / 9135 (0.01%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 3	0 / 1
Lung carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lymphoma			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant neoplasm of renal pelvis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of spermatic cord			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Meningioma			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma benign			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesothelioma			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mesothelioma malignant			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to liver			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Metastases to lung			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to neck			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 9135 (0.00%)	7 / 9108 (0.08%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 7	0 / 5
Oesophageal carcinoma			
subjects affected / exposed	2 / 9135 (0.02%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Pancreatic carcinoma			
subjects affected / exposed	4 / 9135 (0.04%)	2 / 9108 (0.02%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 5
Pancreatic carcinoma metastatic			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Papillary thyroid cancer			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile cancer			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer metastatic			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Plasma cell myeloma			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Polycythaemia vera			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer recurrent			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	3 / 9135 (0.03%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal cancer			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal cancer			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Skin cancer			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of lung			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Small intestine carcinoma metastatic			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tongue neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Squamous cell carcinoma of the cervix			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsil cancer			

subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Uterine leiomyoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal cancer			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Lung cancer metastatic			
subjects affected / exposed	2 / 9135 (0.02%)	5 / 9108 (0.05%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 5	0 / 1
Colon adenoma			
subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to peritoneum			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal cancer metastatic			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Small intestine carcinoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain cancer metastatic			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic cancer metastatic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Rectal cancer metastatic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic carcinoma of the bladder			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Colon cancer metastatic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	15 / 9135 (0.16%)	6 / 9108 (0.07%)	10 / 9109 (0.11%)
occurrences causally related to treatment / all	0 / 15	1 / 6	0 / 10
deaths causally related to treatment / all	0 / 5	0 / 1	0 / 1
Metastases to central nervous system			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural neoplasm			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	20 / 9135 (0.22%)	15 / 9108 (0.16%)	15 / 9109 (0.16%)
occurrences causally related to treatment / all	0 / 21	0 / 16	1 / 15
deaths causally related to treatment / all	0 / 19	0 / 15	0 / 12
Cancer pain			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Benign renal neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal neoplasm			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastatic neoplasm			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Colorectal cancer			

subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Adrenal neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Malignant mesenchymoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral nervous system neoplasm			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic marginal zone lymphoma			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar neoplasm			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal cancer			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Colon cancer stage 0			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ameloblastoma			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder cancer metastatic			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm of unknown primary site			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Hepatic cancer			
subjects affected / exposed	3 / 9135 (0.03%)	5 / 9108 (0.05%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 3	0 / 5	0 / 2
Hepatocellular carcinoma			

subjects affected / exposed	4 / 9135 (0.04%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Central nervous system neuroblastoma			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine benign neoplasm			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal gland cancer			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine tumour of the lung			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Adenocarcinoma metastatic			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Follicular lymphoma			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Aortic aneurysm			
subjects affected / exposed	2 / 9135 (0.02%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic thrombosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Orthostatic hypotension			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			

subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renovascular hypertension			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism arterial			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose ulceration			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis superficial			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery stenosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodynamic instability			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dry gangrene			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery occlusion			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive emergency			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic rupture			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Peripheral venous disease			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	4 / 9135 (0.04%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Peripheral artery aneurysm rupture			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atheroembolism			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Carotid endarterectomy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula operation			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystectomy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery surgery			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot amputation			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polypectomy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia hiatus repair			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia repair			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee arthroplasty			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mole excision			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ptosis repair			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polypectomy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia repair			

subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transurethral prostatectomy			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma surgery			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac pacemaker replacement			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary angioplasty			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus management			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transurethral bladder resection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sigmoidectomy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery angioplasty			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint arthroplasty			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia repair			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin neoplasm excision			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shoulder operation			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth extraction			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract operation			
subjects affected / exposed	2 / 9135 (0.02%)	6 / 9108 (0.07%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 8	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm surgery			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal endoscopic therapy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma closure			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter management			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal polypectomy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	10 / 9135 (0.11%)	6 / 9108 (0.07%)	14 / 9109 (0.15%)
occurrences causally related to treatment / all	0 / 10	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	5 / 9135 (0.05%)	7 / 9108 (0.08%)	6 / 9109 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 5	0 / 7	0 / 6
Generalised oedema			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Euthanasia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pyrexia			
subjects affected / exposed	2 / 9135 (0.02%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nodule			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Unevaluable event			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Accidental death			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Non-cardiac chest pain			
subjects affected / exposed	10 / 9135 (0.11%)	8 / 9108 (0.09%)	6 / 9109 (0.07%)
occurrences causally related to treatment / all	0 / 10	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent-graft endoleak			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular stent stenosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device site erosion			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	3 / 9135 (0.03%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 3	0 / 2	0 / 1
Lithiasis			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Contrast media reaction			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food allergy			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anti-neutrophil cytoplasmic antibody positive vasculitis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Pregnancy of partner			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Prostatic haemorrhage			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic prolapse			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gynaecomastia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign prostatic hyperplasia			
subjects affected / exposed	7 / 9135 (0.08%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Acute respiratory failure			
subjects affected / exposed	5 / 9135 (0.05%)	8 / 9108 (0.09%)	4 / 9109 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 3	0 / 4	0 / 2
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute pulmonary oedema			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 9135 (0.01%)	4 / 9108 (0.04%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 2
Cough			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	6 / 9135 (0.07%)	7 / 9108 (0.08%)	13 / 9109 (0.14%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 13
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Choking			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Laryngeal oedema			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nasal polyps			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	4 / 9135 (0.04%)	5 / 9108 (0.05%)	6 / 9109 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 6	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pleurisy			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary fibrosis			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pulmonary hypertension			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary vasculitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory disorder			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Respiratory distress			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory failure			
subjects affected / exposed	5 / 9135 (0.05%)	9 / 9108 (0.10%)	8 / 9109 (0.09%)
occurrences causally related to treatment / all	0 / 5	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 5	0 / 8	0 / 7
Sleep apnoea syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat irritation			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory acidosis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord polyp			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial polyp			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal mass			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acquired diaphragmatic eventration			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive airways disorder			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough variant asthma			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute interstitial pneumonitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper airway obstruction			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Negative pressure pulmonary oedema			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Delirium			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Depression			

subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mania			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic attack			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stereotypy			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			

subjects affected / exposed	4 / 9135 (0.04%)	3 / 9108 (0.03%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	3 / 9135 (0.03%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	10 / 9135 (0.11%)	12 / 9108 (0.13%)	9 / 9109 (0.10%)
occurrences causally related to treatment / all	0 / 10	0 / 12	0 / 9
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	7 / 9135 (0.08%)	10 / 9108 (0.11%)	8 / 9109 (0.09%)
occurrences causally related to treatment / all	0 / 7	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	5 / 9135 (0.05%)	6 / 9108 (0.07%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			

subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Cirrhosis alcoholic			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis toxic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic mass			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose abnormal			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biopsy prostate			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchoscopy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheterisation cardiac			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonoscopy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIV test positive			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic specific antigen increased			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urological examination			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiogram peripheral			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Computerised tomogram thorax			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood electrolytes abnormal			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiocardiogram			

subjects affected / exposed	10 / 9135 (0.11%)	12 / 9108 (0.13%)	9 / 9109 (0.10%)
occurrences causally related to treatment / all	0 / 12	0 / 14	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis B core antibody positive			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza A virus test positive			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stenotrophomonas test positive			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness traumatic			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Chemical poisoning			

subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fall			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body in eye			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	3 / 9135 (0.03%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gun shot wound			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	4 / 9135 (0.04%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Incisional hernia, obstructive			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning deliberate			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury cervical			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	5 / 9135 (0.05%)	3 / 9108 (0.03%)	4 / 9109 (0.04%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 3
Spinal compression fracture			
subjects affected / exposed	2 / 9135 (0.02%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular injury			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound secretion			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain contusion			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative renal failure			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound necrosis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound evisceration			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pelvic fracture			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder injury			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular bypass dysfunction			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular anastomosis aneurysm			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural swelling			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Airway burns			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Procedural intestinal perforation			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fabry's disease			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 9135 (0.01%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	4 / 9135 (0.04%)	11 / 9108 (0.12%)	7 / 9109 (0.08%)
occurrences causally related to treatment / all	0 / 4	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 9135 (0.01%)	3 / 9108 (0.03%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Cor pulmonale			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cardiac failure chronic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dressler's syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery perforation			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Amyotrophic lateral sclerosis			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amnesia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Altered state of consciousness			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bell's palsy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous thrombosis			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervicobrachial syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia Alzheimer's type			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Demyelination			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			

subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 9135 (0.01%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic coma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Headache			
subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemianopia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Monoplegia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia gravis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve compression			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Neuropathy peripheral			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor neurone disease			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post herpetic neuralgia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal nerve palsy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal lobe epilepsy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	6 / 9135 (0.07%)	7 / 9108 (0.08%)	8 / 9109 (0.09%)
occurrences causally related to treatment / all	0 / 6	1 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 9135 (0.00%)	3 / 9108 (0.03%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Transient ischaemic attack			
subjects affected / exposed	3 / 9135 (0.03%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uraemic encephalopathy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vertebrobasilar insufficiency			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo CNS origin			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamus haemorrhage			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular dementia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cubital tunnel syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Putamen haemorrhage			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain injury			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuromuscular pain			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Haemolytic anaemia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic anaemia			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	14 / 9135 (0.15%)	5 / 9108 (0.05%)	10 / 9109 (0.11%)
occurrences causally related to treatment / all	7 / 15	3 / 5	7 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normocytic anaemia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	4 / 9135 (0.04%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	2 / 4	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 3	1 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	5 / 9135 (0.05%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	2 / 5	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pernicious anaemia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypereosinophilic syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood disorder			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic diathesis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 9135 (0.02%)	6 / 9108 (0.07%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo positional			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular disorder			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deafness bilateral			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoacusis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear discomfort			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden hearing loss			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness transient			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amaurosis fugax			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract cortical			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			

subjects affected / exposed	17 / 9135 (0.19%)	7 / 9108 (0.08%)	11 / 9109 (0.12%)
occurrences causally related to treatment / all	0 / 20	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness unilateral			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract nuclear			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic retinopathy			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmoplegia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular oedema			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pterygium			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal artery occlusion			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vein thrombosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal degeneration			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden visual loss			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual acuity reduced			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous haemorrhage			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	2 / 3	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular hole			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dacryostenosis acquired			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tolosa-Hunt syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Entropion			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal vascular thrombosis			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Age-related macular degeneration			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	4 / 9135 (0.04%)	5 / 9108 (0.05%)	4 / 9109 (0.04%)
occurrences causally related to treatment / all	2 / 4	0 / 5	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	5 / 9135 (0.05%)	5 / 9108 (0.05%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Acute abdomen			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Anal fistula			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Barrett's oesophagus			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	5 / 9135 (0.05%)	3 / 9108 (0.03%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 5	0 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flatulence			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallstone ileus			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	6 / 9135 (0.07%)	5 / 9108 (0.05%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	3 / 7	1 / 5	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis alcoholic			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	5 / 9135 (0.05%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	5 / 7	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	6 / 9135 (0.07%)	5 / 9108 (0.05%)	4 / 9109 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Large intestine perforation			
subjects affected / exposed	1 / 9135 (0.01%)	3 / 9108 (0.03%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal obstruction			
subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			

subjects affected / exposed	4 / 9135 (0.04%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	3 / 4	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal achalasia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	6 / 9135 (0.07%)	12 / 9108 (0.13%)	12 / 9109 (0.13%)
occurrences causally related to treatment / all	0 / 6	0 / 13	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 3
Pancreatitis haemorrhagic			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 2
Pancreatitis chronic			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			

subjects affected / exposed	6 / 9135 (0.07%)	13 / 9108 (0.14%)	7 / 9109 (0.08%)
occurrences causally related to treatment / all	1 / 6	1 / 13	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer haemorrhage			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spigelian hernia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia, obstructive			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vomiting			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic mass			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Subileus			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal haemorrhage			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyschezia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			

subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastric antral vascular ectasia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	8 / 9135 (0.09%)	9 / 9108 (0.10%)	15 / 9109 (0.16%)
occurrences causally related to treatment / all	0 / 8	0 / 9	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal rupture			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholic pancreatitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal toxicity			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric mucosal lesion			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia strangulated			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic enteritis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Omental infarction			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal incarcerated hernia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subacute pancreatitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive pancreatitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Decubitus ulcer			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angioedema			
subjects affected / exposed	1 / 9135 (0.01%)	5 / 9108 (0.05%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 3	1 / 5	2 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ingrowing nail			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity vasculitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema multiforme			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperhidrosis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen planus			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatomyositis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash pruritic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin necrosis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash erythematous			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	2 / 3	0 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pemphigoid			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoplakia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria chronic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Capillaritis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Azotaemia			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	6 / 9135 (0.07%)	4 / 9108 (0.04%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	8 / 9135 (0.09%)	6 / 9108 (0.07%)	6 / 9109 (0.07%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 2	0 / 4	0 / 2
Renal tubular necrosis			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder mass			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic nephropathy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal impairment			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	4 / 9135 (0.04%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urogenital disorder			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Chronic kidney disease			

subjects affected / exposed	4 / 9135 (0.04%)	4 / 9108 (0.04%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Stress urinary incontinence			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	32 / 9135 (0.35%)	22 / 9108 (0.24%)	25 / 9109 (0.27%)
occurrences causally related to treatment / all	0 / 33	0 / 22	0 / 25
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Prerenal failure			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism primary			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's disease			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic nodular goitre			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty arthritis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle atrophy			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopathy			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	5 / 9135 (0.05%)	8 / 9108 (0.09%)	6 / 9109 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthropathy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoporotic fracture			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 9135 (0.00%)	4 / 9108 (0.04%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia rheumatica			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondyloarthropathy			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seronegative arthritis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facet joint syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal synovial cyst			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal stenosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess oral			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	4 / 9135 (0.04%)	1 / 9108 (0.01%)	8 / 9109 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	3 / 9135 (0.03%)	3 / 9108 (0.03%)	4 / 9109 (0.04%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cellulitis			
subjects affected / exposed	11 / 9135 (0.12%)	9 / 9108 (0.10%)	11 / 9109 (0.12%)
occurrences causally related to treatment / all	0 / 11	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cystitis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dengue fever			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	7 / 9135 (0.08%)	3 / 9108 (0.03%)	4 / 9109 (0.04%)
occurrences causally related to treatment / all	0 / 7	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gangrene			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis infected			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis viral			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear lobe infection			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis intestinal haemorrhagic			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiglottitis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fournier's gangrene			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	4 / 9135 (0.04%)	6 / 9108 (0.07%)	8 / 9109 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 7	0 / 8
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Gastroenteritis			
subjects affected / exposed	5 / 9135 (0.05%)	5 / 9108 (0.05%)	6 / 9109 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	4 / 9135 (0.04%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 9135 (0.01%)	3 / 9108 (0.03%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Mediastinitis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			

subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Meningitis aseptic			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising fasciitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media chronic			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	19 / 9135 (0.21%)	28 / 9108 (0.31%)	27 / 9109 (0.30%)
occurrences causally related to treatment / all	0 / 21	0 / 28	0 / 32
deaths causally related to treatment / all	0 / 13	0 / 16	0 / 17
Pharyngitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Periodontitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	3 / 9135 (0.03%)	3 / 9108 (0.03%)	4 / 9109 (0.04%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	3 / 9135 (0.03%)	3 / 9108 (0.03%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal abscess			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	22 / 9135 (0.24%)	19 / 9108 (0.21%)	18 / 9109 (0.20%)
occurrences causally related to treatment / all	0 / 24	0 / 19	0 / 18
deaths causally related to treatment / all	0 / 13	0 / 11	0 / 8
Skin infection			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	4 / 9135 (0.04%)	9 / 9108 (0.10%)	8 / 9109 (0.09%)
occurrences causally related to treatment / all	0 / 4	0 / 9	0 / 8
deaths causally related to treatment / all	0 / 4	0 / 8	0 / 5
Subcutaneous abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	18 / 9135 (0.20%)	11 / 9108 (0.12%)	17 / 9109 (0.19%)
occurrences causally related to treatment / all	0 / 20	0 / 11	0 / 19
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 9135 (0.02%)	9 / 9108 (0.10%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	11 / 9135 (0.12%)	9 / 9108 (0.10%)	7 / 9109 (0.08%)
occurrences causally related to treatment / all	0 / 11	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Anal abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal abscess			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	2 / 9135 (0.02%)	3 / 9108 (0.03%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 1
Neuroborreliosis			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			

subjects affected / exposed	0 / 9135 (0.00%)	3 / 9108 (0.03%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Helicobacter infection			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia necrotising			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Subdiaphragmatic abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Biliary sepsis			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Wound sepsis			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infected cyst			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral toxoplasmosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site infection			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			

subjects affected / exposed	1 / 9135 (0.01%)	2 / 9108 (0.02%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Intervertebral discitis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella infection			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Borrelia infection			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical mycobacterial infection			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterial infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis bacterial			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratitis bacterial			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 9135 (0.00%)	2 / 9108 (0.02%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cholecystitis infective			

subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection bacterial			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural sepsis			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infectious pleural effusion			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	3 / 9135 (0.03%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic abscess			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device site joint infection			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis infective			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial abdominal infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 3
Nephritis bacterial			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	5 / 9135 (0.05%)	6 / 9108 (0.07%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 6	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 9135 (0.01%)	5 / 9108 (0.05%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	4 / 9135 (0.04%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Diabetic ketoacidosis			
subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cachexia			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	2 / 9109 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fluid overload			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			

subjects affected / exposed	1 / 9135 (0.01%)	1 / 9108 (0.01%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperammonaemia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	3 / 9135 (0.03%)	1 / 9108 (0.01%)	3 / 9109 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Hypomagnesaemia			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	2 / 9135 (0.02%)	1 / 9108 (0.01%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 9135 (0.01%)	3 / 9108 (0.03%)	5 / 9109 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			

subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lactic acidosis			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 9135 (0.00%)	1 / 9108 (0.01%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic complication			
subjects affected / exposed	0 / 9135 (0.00%)	0 / 9108 (0.00%)	1 / 9109 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Marasmus			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 9135 (0.01%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic metabolic decompensation			
subjects affected / exposed	2 / 9135 (0.02%)	0 / 9108 (0.00%)	0 / 9109 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0.1 %

Non-serious adverse events	Rivaroxaban 2.5mg + Aspirin 100mg	Rivaroxaban Placebo + Aspirin 100mg	Rivaroxaban 5mg + Aspirin Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	569 / 9135 (6.23%)	526 / 9108 (5.78%)	540 / 9109 (5.93%)
Vascular disorders			
Hypertension			
subjects affected / exposed	25 / 9135 (0.27%)	12 / 9108 (0.13%)	16 / 9109 (0.18%)
occurrences (all)	25	13	18
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	5 / 9135 (0.05%)	10 / 9108 (0.11%)	3 / 9109 (0.03%)
occurrences (all)	5	10	4
Pyrexia			
subjects affected / exposed	6 / 9135 (0.07%)	8 / 9108 (0.09%)	10 / 9109 (0.11%)
occurrences (all)	6	9	10
Oedema peripheral			
subjects affected / exposed	3 / 9135 (0.03%)	12 / 9108 (0.13%)	7 / 9109 (0.08%)
occurrences (all)	7	15	8
Chest pain			
subjects affected / exposed	7 / 9135 (0.08%)	10 / 9108 (0.11%)	9 / 9109 (0.10%)
occurrences (all)	11	10	12
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 9135 (0.08%)	11 / 9108 (0.12%)	12 / 9109 (0.13%)
occurrences (all)	9	13	18
Epistaxis			
subjects affected / exposed	38 / 9135 (0.42%)	25 / 9108 (0.27%)	29 / 9109 (0.32%)
occurrences (all)	73	30	45
Haemoptysis			
subjects affected / exposed	10 / 9135 (0.11%)	5 / 9108 (0.05%)	5 / 9109 (0.05%)
occurrences (all)	25	5	6
Upper respiratory tract inflammation			
subjects affected / exposed	10 / 9135 (0.11%)	4 / 9108 (0.04%)	8 / 9109 (0.09%)
occurrences (all)	11	4	9
Psychiatric disorders			
Insomnia			

subjects affected / exposed	7 / 9135 (0.08%)	4 / 9108 (0.04%)	12 / 9109 (0.13%)
occurrences (all)	8	4	14
Investigations			
Occult blood positive			
subjects affected / exposed	12 / 9135 (0.13%)	3 / 9108 (0.03%)	7 / 9109 (0.08%)
occurrences (all)	12	4	7
Injury, poisoning and procedural complications			
Skin abrasion			
subjects affected / exposed	11 / 9135 (0.12%)	3 / 9108 (0.03%)	4 / 9109 (0.04%)
occurrences (all)	12	3	4
Contusion			
subjects affected / exposed	37 / 9135 (0.41%)	28 / 9108 (0.31%)	23 / 9109 (0.25%)
occurrences (all)	42	43	27
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	26 / 9135 (0.28%)	22 / 9108 (0.24%)	19 / 9109 (0.21%)
occurrences (all)	44	33	34
Nervous system disorders			
Dizziness			
subjects affected / exposed	25 / 9135 (0.27%)	36 / 9108 (0.40%)	26 / 9109 (0.29%)
occurrences (all)	41	43	38
Headache			
subjects affected / exposed	21 / 9135 (0.23%)	23 / 9108 (0.25%)	21 / 9109 (0.23%)
occurrences (all)	32	33	32
Hypoaesthesia			
subjects affected / exposed	7 / 9135 (0.08%)	12 / 9108 (0.13%)	8 / 9109 (0.09%)
occurrences (all)	7	15	9
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	8 / 9135 (0.09%)	1 / 9108 (0.01%)	12 / 9109 (0.13%)
occurrences (all)	10	1	16
Anaemia			
subjects affected / exposed	16 / 9135 (0.18%)	10 / 9108 (0.11%)	12 / 9109 (0.13%)
occurrences (all)	27	13	14
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	10 / 9135 (0.11%)	15 / 9108 (0.16%)	13 / 9109 (0.14%)
occurrences (all)	13	19	19
Eye disorders			
Cataract			
subjects affected / exposed	12 / 9135 (0.13%)	12 / 9108 (0.13%)	15 / 9109 (0.16%)
occurrences (all)	12	13	16
Conjunctival haemorrhage			
subjects affected / exposed	10 / 9135 (0.11%)	3 / 9108 (0.03%)	11 / 9109 (0.12%)
occurrences (all)	13	3	14
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	18 / 9135 (0.20%)	11 / 9108 (0.12%)	11 / 9109 (0.12%)
occurrences (all)	33	20	22
Diarrhoea			
subjects affected / exposed	48 / 9135 (0.53%)	31 / 9108 (0.34%)	58 / 9109 (0.64%)
occurrences (all)	65	39	79
Abdominal pain			
subjects affected / exposed	8 / 9135 (0.09%)	3 / 9108 (0.03%)	12 / 9109 (0.13%)
occurrences (all)	12	3	23
Abdominal pain upper			
subjects affected / exposed	31 / 9135 (0.34%)	22 / 9108 (0.24%)	19 / 9109 (0.21%)
occurrences (all)	48	30	32
Dental caries			
subjects affected / exposed	15 / 9135 (0.16%)	10 / 9108 (0.11%)	12 / 9109 (0.13%)
occurrences (all)	15	10	13
Gastritis			
subjects affected / exposed	19 / 9135 (0.21%)	13 / 9108 (0.14%)	7 / 9109 (0.08%)
occurrences (all)	28	21	7
Constipation			
subjects affected / exposed	26 / 9135 (0.28%)	24 / 9108 (0.26%)	18 / 9109 (0.20%)
occurrences (all)	33	37	20
Nausea			
subjects affected / exposed	21 / 9135 (0.23%)	17 / 9108 (0.19%)	18 / 9109 (0.20%)
occurrences (all)	30	25	28
Dyspepsia			

subjects affected / exposed	14 / 9135 (0.15%)	15 / 9108 (0.16%)	13 / 9109 (0.14%)
occurrences (all)	19	24	22
Large intestine polyp			
subjects affected / exposed	17 / 9135 (0.19%)	8 / 9108 (0.09%)	12 / 9109 (0.13%)
occurrences (all)	18	8	14
Vomiting			
subjects affected / exposed	8 / 9135 (0.09%)	11 / 9108 (0.12%)	8 / 9109 (0.09%)
occurrences (all)	9	14	9
Gingival bleeding			
subjects affected / exposed	11 / 9135 (0.12%)	6 / 9108 (0.07%)	11 / 9109 (0.12%)
occurrences (all)	13	7	13
Stomatitis			
subjects affected / exposed	12 / 9135 (0.13%)	4 / 9108 (0.04%)	12 / 9109 (0.13%)
occurrences (all)	12	4	12
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	17 / 9135 (0.19%)	20 / 9108 (0.22%)	19 / 9109 (0.21%)
occurrences (all)	23	22	25
Haemorrhage subcutaneous			
subjects affected / exposed	49 / 9135 (0.54%)	17 / 9108 (0.19%)	18 / 9109 (0.20%)
occurrences (all)	86	29	23
Pruritus			
subjects affected / exposed	19 / 9135 (0.21%)	18 / 9108 (0.20%)	23 / 9109 (0.25%)
occurrences (all)	27	22	37
Urticaria			
subjects affected / exposed	11 / 9135 (0.12%)	6 / 9108 (0.07%)	11 / 9109 (0.12%)
occurrences (all)	13	7	11
Rash			
subjects affected / exposed	12 / 9135 (0.13%)	19 / 9108 (0.21%)	18 / 9109 (0.20%)
occurrences (all)	22	31	33
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	24 / 9135 (0.26%)	8 / 9108 (0.09%)	15 / 9109 (0.16%)
occurrences (all)	34	10	25
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	28 / 9135 (0.31%)	30 / 9108 (0.33%)	26 / 9109 (0.29%)
occurrences (all)	32	36	31
Back pain			
subjects affected / exposed	25 / 9135 (0.27%)	25 / 9108 (0.27%)	37 / 9109 (0.41%)
occurrences (all)	27	27	39
Lumbar spinal stenosis			
subjects affected / exposed	10 / 9135 (0.11%)	6 / 9108 (0.07%)	5 / 9109 (0.05%)
occurrences (all)	10	6	5
Myalgia			
subjects affected / exposed	6 / 9135 (0.07%)	13 / 9108 (0.14%)	14 / 9109 (0.15%)
occurrences (all)	7	14	18
Spinal osteoarthritis			
subjects affected / exposed	10 / 9135 (0.11%)	8 / 9108 (0.09%)	7 / 9109 (0.08%)
occurrences (all)	10	8	7
Osteoarthritis			
subjects affected / exposed	5 / 9135 (0.05%)	8 / 9108 (0.09%)	10 / 9109 (0.11%)
occurrences (all)	7	10	10
Pain in extremity			
subjects affected / exposed	14 / 9135 (0.15%)	9 / 9108 (0.10%)	8 / 9109 (0.09%)
occurrences (all)	19	12	10
Muscle spasms			
subjects affected / exposed	10 / 9135 (0.11%)	6 / 9108 (0.07%)	10 / 9109 (0.11%)
occurrences (all)	11	9	12
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	188 / 9135 (2.06%)	195 / 9108 (2.14%)	181 / 9109 (1.99%)
occurrences (all)	284	289	284
Herpes zoster			
subjects affected / exposed	9 / 9135 (0.10%)	19 / 9108 (0.21%)	15 / 9109 (0.16%)
occurrences (all)	9	21	15
Gastroenteritis			
subjects affected / exposed	16 / 9135 (0.18%)	10 / 9108 (0.11%)	10 / 9109 (0.11%)
occurrences (all)	21	11	10
Bronchitis			

subjects affected / exposed	14 / 9135 (0.15%)	13 / 9108 (0.14%)	7 / 9109 (0.08%)
occurrences (all)	15	13	7
Cystitis			
subjects affected / exposed	6 / 9135 (0.07%)	7 / 9108 (0.08%)	10 / 9109 (0.11%)
occurrences (all)	6	7	13
Influenza			
subjects affected / exposed	18 / 9135 (0.20%)	24 / 9108 (0.26%)	14 / 9109 (0.15%)
occurrences (all)	18	25	16
Periodontitis			
subjects affected / exposed	12 / 9135 (0.13%)	12 / 9108 (0.13%)	11 / 9109 (0.12%)
occurrences (all)	13	12	11
Pharyngitis			
subjects affected / exposed	8 / 9135 (0.09%)	10 / 9108 (0.11%)	7 / 9109 (0.08%)
occurrences (all)	8	11	7
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	26 / 9135 (0.28%)	28 / 9108 (0.31%)	16 / 9109 (0.18%)
occurrences (all)	27	28	16

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 July 2014	Amendment 6 formed integrated protocol version 2.0. The major modifications specified in Amendment 6 were simplified and clarified eligibility criteria for the study population of subjects with CAD and PAD and an increase of the sample size from 19500 to ~21400 randomized subjects.
19 August 2015	Amendment 8 formed integrated protocol version 3.0. The main modification due to Amendment 8 was a modification of the secondary outcomes to include 2 new composites of major thrombotic events, including new outcome components (ALI and CHD death). The multiple testing strategy was revised to ensure the control of the familywise type I error for both testing of primary and secondary efficacy variables for the final analyses based on 2200 events. The statistical analysis plan (SAP) was updated according to the advice received by the Food and Drug Administration (FDA) in the letter received in AUG 2014: the description for the analysis in the case where only 1 of the 2 interventional arms is continued after an interim analysis. Furthermore, the number of subjects in the trial was increased to at least 27400 randomized subjects.
12 September 2017	Amendment 11 formed integrated protocol version 4.0. The main modification due to Amendment 11 was the addition of the COMPASS LTOLE phase to make rivaroxaban 2.5 mg bid plus aspirin 100 mg od available to the study subjects prior to commercial availability. For this purpose, a final rivaroxaban/aspirin follow-up visit and a rivaroxaban/aspirin washout visit was introduced while the pantoprazole treatment continued.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28754388

http://www.ncbi.nlm.nih.gov/pubmed/28844192

http://www.ncbi.nlm.nih.gov/pubmed/28844176

http://www.ncbi.nlm.nih.gov/pubmed/29372976

http://www.ncbi.nlm.nih.gov/pubmed/29132879

http://www.ncbi.nlm.nih.gov/pubmed/29132880

http://www.ncbi.nlm.nih.gov/pubmed/29132877

http://www.ncbi.nlm.nih.gov/pubmed/29186454

http://www.ncbi.nlm.nih.gov/pubmed/29661947

http://www.ncbi.nlm.nih.gov/pubmed/29540326

http://www.ncbi.nlm.nih.gov/pubmed/29945212

http://www.ncbi.nlm.nih.gov/pubmed/30058959

http://www.ncbi.nlm.nih.gov/pubmed/29346127

http://www.ncbi.nlm.nih.gov/pubmed/30220379

http://www.ncbi.nlm.nih.gov/pubmed/30417662

http://www.ncbi.nlm.nih.gov/pubmed/30653475

http://www.ncbi.nlm.nih.gov/pubmed/30213508

http://www.ncbi.nlm.nih.gov/pubmed/30354448

http://www.ncbi.nlm.nih.gov/pubmed/30654882

http://www.ncbi.nlm.nih.gov/pubmed/30667279

http://www.ncbi.nlm.nih.gov/pubmed/30702997

http://www.ncbi.nlm.nih.gov/pubmed/31054846

http://www.ncbi.nlm.nih.gov/pubmed/31072566

http://www.ncbi.nlm.nih.gov/pubmed/31146821

http://www.ncbi.nlm.nih.gov/pubmed/31152740

http://www.ncbi.nlm.nih.gov/pubmed/31144674

http://www.ncbi.nlm.nih.gov/pubmed/31510769

http://www.ncbi.nlm.nih.gov/pubmed/31524941

http://www.ncbi.nlm.nih.gov/pubmed/30916315

http://www.ncbi.nlm.nih.gov/pubmed/34191011

http://www.ncbi.nlm.nih.gov/pubmed/31163978

http://www.ncbi.nlm.nih.gov/pubmed/31248549

http://www.ncbi.nlm.nih.gov/pubmed/31248548

http://www.ncbi.nlm.nih.gov/pubmed/31321405

http://www.ncbi.nlm.nih.gov/pubmed/31358978

http://www.ncbi.nlm.nih.gov/pubmed/31504399

http://www.ncbi.nlm.nih.gov/pubmed/31537259

http://www.ncbi.nlm.nih.gov/pubmed/31615291

http://www.ncbi.nlm.nih.gov/pubmed/31807773

http://www.ncbi.nlm.nih.gov/pubmed/31715433

http://www.ncbi.nlm.nih.gov/pubmed/30538057

http://www.ncbi.nlm.nih.gov/pubmed/32178526

http://www.ncbi.nlm.nih.gov/pubmed/32289159

http://www.ncbi.nlm.nih.gov/pubmed/32223318

http://www.ncbi.nlm.nih.gov/pubmed/32436455

http://www.ncbi.nlm.nih.gov/pubmed/32951537

http://www.ncbi.nlm.nih.gov/pubmed/32997098

http://www.ncbi.nlm.nih.gov/pubmed/33538248

http://www.ncbi.nlm.nih.gov/pubmed/33957178

http://www.ncbi.nlm.nih.gov/pubmed/34021038

http://www.ncbi.nlm.nih.gov/pubmed/34132753

http://www.ncbi.nlm.nih.gov/pubmed/34210409

http://www.ncbi.nlm.nih.gov/pubmed/34463737

http://www.ncbi.nlm.nih.gov/pubmed/35383832