Clinical trial results:
A long-term, randomised, double-blind, placebo-controlled, multinational, multi-centre trial to evaluate cardiovascular and other long-term outcomes with semaglutide in subjects with type 2 diabetes

Summary

EudraCT number	2012-002839-28
Trial protocol	GB ES BG DE DK PL IT
Global end of trial date	15 March 2016

Results information

Result version number	v1 (current)
This version publication date	31 March 2017
First version publication date	31 March 2017

Trial information

Trial identification

Sponsor protocol code	NN9535-3744

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01720446
WHO universal trial number (UTN)	U1111-1131-7227

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Global Clinical Registry (GCR, 1452), Novo Nordisk A/S, clinicaltrials@novonordisk.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	24 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2016
Global end of trial reached?	Yes
Global end of trial date	15 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To confirm that treatment with semaglutide does not result in an unacceptable increase in cardiovascular risk as compared to placebo in adults with type 2 diabetes. This is done by demonstrating that the upper limit of the two-sided 95% confidence interval (CI) of the hazard ratio for semaglutide versus placebo is less than 1.8 when comparing time to first occurrence of a major adverse cardiovascular event (MACE).

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki, ICH Good Clinical Practice, EN ISO 14155 Part 1 and 2 and FDA 21 CFR 312.120.

Background therapy:

All participating subjects received the best standard-of-care in addition to the trial products and, to the extent possible, achieved optimal glycaemic control according to local standards (additional glucose lowering medications could be added to the anti-diabetic regimen at the discretion of investigator).

Evidence for comparator:

Not applicable

Actual start date of recruitment	21 February 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 166
Country: Number of subjects enrolled	Australia: 111
Country: Number of subjects enrolled	Bulgaria: 101
Country: Number of subjects enrolled	Brazil: 105
Country: Number of subjects enrolled	Canada: 138
Country: Number of subjects enrolled	Germany: 85
Country: Number of subjects enrolled	Denmark: 66
Country: Number of subjects enrolled	Algeria: 95
Country: Number of subjects enrolled	Spain: 85
Country: Number of subjects enrolled	United Kingdom: 117
Country: Number of subjects enrolled	Israel: 100
Country: Number of subjects enrolled	Italy: 80
Country: Number of subjects enrolled	Mexico: 165
Country: Number of subjects enrolled	Malaysia: 70
Country: Number of subjects enrolled	Poland: 98

Country: Number of subjects enrolled	Russian Federation: 294
Country: Number of subjects enrolled	Thailand: 74
Country: Number of subjects enrolled	Turkey: 128
Country: Number of subjects enrolled	Taiwan: 82
Country: Number of subjects enrolled	United States: 1137
Worldwide total number of subjects	3297
EEA total number of subjects	632

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)	1699
From 65 to 84 years	1578
85 years and over	20

Subject disposition

Recruitment

Recruitment details:

The trial was conducted at 229 sites in 20 countries. Country (sites): Algeria (4), Argentina (7), Australia (8), Brazil (8), Bulgaria (5), Canada (13), Denmark (5), Germany (7), Israel (6), Italy (6), Malaysia (6), Mexico (9), Poland (5), Russia (11), Spain (6), Taiwan (4), Thailand (5), Turkey (10), United Kingdom (8) and United States (96).

Pre-assignment

Screening details:

The trial population was subjects with T2D with inadequate glycaemic control (HbA1c ≥ 7%) at high CV risk. The trial included subjects ≥ 50 years of age at screening with clinical evidence of CV disease and subjects ≥ 60 years of age at screening with subclinical evidence of CV disease.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Semaglutide 0.5 mg

Arm description:

Subjects received once-weekly dose of semaglutide 0.5 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment. Each subject was treated for 104 weeks.

Arm type	Experimental
Investigational medicinal product name	Semaglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Semaglutide solution for injection (1.34 mg/mL in a 1.5 mL pre-filled PDS290 pen-injector) was administered in doses
of 0.5 mg once-weekly as subcutaneous (s.c.) injections either in the thigh, abdomen or upper arm, at any time of day irrespective of meals. Subjects started with doses of 0.25 mg semaglutide. After 4 weeks of treatment, the dose was escalated (doubled). Hence, the target dose of 0.5 mg was achieved after 4 weeks of treatment.

Arm title	Semaglutide 1.0 mg

Arm description:

Subjects received once-weekly dose of semaglutide 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.

Arm type	Experimental

Investigational medicinal product name	Semaglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Semaglutide solution for injection (1.34 mg/mL in a 1.5 mL pre-filled PDS290 pen-injector) was administered in doses
of 1.0 mg once-weekly as subcutaneous (s.c.) injections either in the thigh, abdomen or upper arm, at any time of day irrespective of meals. Subjects started with doses of 0.25 mg semaglutide. After 4 weeks of treatment, the dose was escalated (doubled). Hence, the target dose of 1.0 mg was achieved after 8 weeks of treatment.

Arm title	Placebo 0.5 mg

Arm description:

Subjects received once-weekly dose of placebo 0.5 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment. Each subject was treated for 104 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

The composition of the placebo corresponded to that of semaglutide drug product but with absence of the active pharmaceutical ingredient. Placebo solution for injection (1.34 mg/mL in a 1.5 mL pre-filled PDS290 pen-injector) was administered in doses of 0.5 mg once-weekly as subcutaneous (s.c.) injections either in the thigh, abdomen or upper arm, at any time of day irrespective of meals. Subjects started with doses of 0.25 mg semaglutide. After 4 weeks of treatment, the dose was escalated (doubled). Hence, the target dose of 0.5 mg was achieved after 4 weeks of treatment.

Arm title	Placebo 1.0 mg

Arm description:

Subjects received once-weekly dose of placebo 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

The composition of the placebo corresponded to that of semaglutide drug product but with absence of the active pharmaceutical ingredient. Placebo solution for injection (1.34 mg/mL in a 1.5 mL pre-filled PDS290 pen-injector) was administered in doses of 1.0 mg once-weekly as subcutaneous (s.c.) injections either in the thigh, abdomen or upper arm, at any time of day irrespective of meals. Subjects started with doses of 0.25 mg semaglutide. After 4 weeks of treatment, the dose was escalated (doubled). Hence, target dose of 1.0 mg was achieved after 8 weeks of treatment.

Number of subjects in period 1	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg
Started	826	822	824
Completed	812	811	804
Not completed	14	11	20
Consent withdrawn by subject	2	5	4
Lost to follow-up	12	6	16

Number of subjects in period 1	Placebo 1.0 mg
Started	825
Completed	805
Not completed	20
Consent withdrawn by subject	4
Lost to follow-up	16

Baseline characteristics

Reporting groups	
Reporting group title	Semaglutide 0.5 mg
Reporting group description:	
Subjects received once-weekly dose of semaglutide 0.5 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment. Each subject was treated for 104 weeks.	
Reporting group title	Semaglutide 1.0 mg
Reporting group description:	
Subjects received once-weekly dose of semaglutide 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.	
Reporting group title	Placebo 0.5 mg
Reporting group description:	
Subjects received once-weekly dose of placebo 0.5 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment. Each subject was treated for 104 weeks.	
Reporting group title	Placebo 1.0 mg
Reporting group description:	
Subjects received once-weekly dose of placebo 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.	

Reporting group values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg
Number of subjects	826	822	824
Age Categorical Units: Subjects			
Adults (18-64 years)	440	415	419
From 65-84 years	383	400	399
85 years and over	3	7	6
Age Continuous Units: years			
arithmetic mean	64.6	64.7	64.8
standard deviation	± 7.3	± 7.1	± 7.6
Gender Categorical Units: Subjects			
Female	331	304	342
Male	495	518	482
Glycosylated haemoglobin Units: percentage of glycosylated haemoglobin			
arithmetic mean	8.67	8.73	8.7

standard deviation	± 1.39	± 1.51	± 1.49
Fasting plasma glucose Units: mg/dL			
arithmetic mean	185.4	182.9	185.8
standard deviation	± 66.09	± 68.04	± 68.23
Body weight Units: kg			
arithmetic mean	91.8	92.86	91.83
standard deviation	± 20.25	± 21.05	± 20.35
LDL-cholesterol Units: mg/dL			
arithmetic mean	89.62	89.72	89.01
standard deviation	± 39.08	± 34.49	± 38.35
HDL-cholesterol Units: mg/dL			
arithmetic mean	45.92	44.97	45.82
standard deviation	± 13	± 12.42	± 12.92
Total cholesterol Units: mg/dL			
geometric mean	165.38	164.96	164.38
full range (min-max)	65.25 to 632.43	79.54 to 562.16	70.27 to 378.38
Triglycerides Units: mg/dL			
geometric mean	163.66	158.93	162.3
full range (min-max)	27.59 to 1913.5	10.68 to 3378.44	30.26 to 1438.24
Free fatty acids Units: mmol/L			
geometric mean	0.83	0.8	0.83
full range (min-max)	0.04 to 3.82	0.04 to 4.2	0.04 to 3.34
Systolic blood pressure Units: mmHg			
arithmetic mean	136.1	135.8	135.8
standard deviation	± 17.97	± 16.98	± 16.16
Diastolic blood pressure Units: mmHg			
arithmetic mean	77.1	76.88	77.54
standard deviation	± 9.78	± 10.21	± 9.85
Pulse rate Units: beats/min			
arithmetic mean	72.69	71.53	72.01
standard deviation	± 11.22	± 10.86	± 10.62

Reporting group values	Placebo 1.0 mg	Total	
Number of subjects	825	3297	
Age Categorical Units: Subjects			
Adults (18-64 years)	425	1699	
From 65-84 years	396	1578	
85 years and over	4	20	

Age Continuous			
Units: years			
arithmetic mean	64.4		
standard deviation	± 7.5	-	
Gender Categorical			
Units: Subjects			
Female	318	1295	
Male	507	2002	
Glycosylated haemoglobin			
Units: percentage of glycosylated haemoglobin			
arithmetic mean	8.7		
standard deviation	± 1.45	-	
Fasting plasma glucose			
Units: mg/dL			
arithmetic mean	184.6		
standard deviation	± 63.08	-	
Body weight			
Units: kg			
arithmetic mean	91.9		
standard deviation	± 20.75	-	
LDL-cholesterol			
Units: mg/dL			
arithmetic mean	91.14		
standard deviation	± 37.9	-	
HDL-cholesterol			
Units: mg/dL			
arithmetic mean	44.61		
standard deviation	± 12.26	-	
Total cholesterol			
Units: mg/dL			
geometric mean	165.97		
full range (min-max)	64.86 to 537.07	-	
Triglycerides			
Units: mg/dL			
geometric mean	163		
full range (min-max)	35.6 to 2435.93	-	
Free fatty acids			
Units: mmol/L			
geometric mean	0.81		
full range (min-max)	0.04 to 4.22	-	
Systolic blood pressure			
Units: mmHg			
arithmetic mean	134.8		
standard deviation	± 17.45	-	
Diastolic blood pressure			
Units: mmHg			
arithmetic mean	76.66		
standard deviation	± 10.21	-	
Pulse rate			
Units: beats/min			
arithmetic mean	71.95		

standard deviation	± 10.92	-	

Subject analysis sets

Subject analysis set title	Semaglutide
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received once-weekly dose of semaglutide 0.5 mg or 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment and the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received once-weekly dose of placebo 0.5 mg or 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Placebo was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment and the target dose of 1.0 mg was achieved after 8 weeks of treatment . Each subject was treated for 104 weeks.

Reporting group values	Semaglutide	Placebo	
Number of subjects	1648	1649	
Age Categorical Units: Subjects			
Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
arithmetic mean	64.7	64.6	
standard deviation	± 7.2	± 7.5	
Gender Categorical Units: Subjects			
Female Male			
Glycosylated haemoglobin Units: percentage of glycosylated haemoglobin			
arithmetic mean			
standard deviation	±	±	
Fasting plasma glucose Units: mg/dL			
arithmetic mean			
standard deviation	±	±	
Body weight Units: kg			
arithmetic mean			
standard deviation	±	±	
LDL-cholesterol			

Units: mg/dL arithmetic mean standard deviation	± 	± 	
HDL-cholesterol Units: mg/dL arithmetic mean standard deviation	± 	± 	
Total cholesterol Units: mg/dL geometric mean full range (min-max)	 	 	
Triglycerides Units: mg/dL geometric mean full range (min-max)	 	 	
Free fatty acids Units: mmol/L geometric mean full range (min-max)	 	 	
Systolic blood pressure Units: mmHg arithmetic mean standard deviation	 ±	 ±	
Diastolic blood pressure Units: mmHg arithmetic mean standard deviation	 ±	 ±	
Pulse rate Units: beats/min arithmetic mean standard deviation	 ±	 ±	

End points reporting groups

Reporting group title	Semaglutide 0.5 mg

Reporting group description:

Subjects received once-weekly dose of semaglutide 0.5 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment. Each subject was treated for 104 weeks.

Reporting group title	Semaglutide 1.0 mg

Reporting group description:

Subjects received once-weekly dose of semaglutide 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.

Reporting group title	Placebo 0.5 mg

Reporting group description:

Subjects received once-weekly dose of placebo 0.5 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment. Each subject was treated for 104 weeks.

Reporting group title	Placebo 1.0 mg

Reporting group description:

Subjects received once-weekly dose of placebo 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.

Subject analysis set title	Semaglutide
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received once-weekly dose of semaglutide 0.5 mg or 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Semaglutide was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment and the target dose of 1.0 mg was achieved after 8 weeks of treatment. Each subject was treated for 104 weeks.

Subject analysis set title	Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects received once-weekly dose of placebo 0.5 mg or 1.0 mg as an add-on to their standard-of-care treatment. Injections were administered subcutaneously in the thigh, abdomen or upper arm, at any time of day irrespective of meals. The injections were to be administered on the same weekday during the trial. Placebo was initiated at a dose of 0.25 mg and was escalated (doubled) to 0.5 mg after 4 weeks. Hence the target dose of 0.5 mg was achieved after 4 weeks of treatment and the target dose of 1.0 mg was achieved after 8 weeks of treatment . Each subject was treated for 104 weeks.

Primary: Time from randomisation to first occurrence of a MACE, defined as cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke.

End point title	Time from randomisation to first occurrence of a MACE, defined as cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke.

End point description:

Proportion of subjects experiencing a first event of a MACE, defined as cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke.

End point type	Primary

End point timeframe:

Time from randomisation to first occurrence of an expanded composite cardiovascular outcome.

End point values	Semaglutide	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1648	1649		
Units: proportion of subjects				
number (not applicable)	6.6	8.9		

Statistical analyses

Statistical analysis title	Non-Inferiority

Statistical analysis description:

The primary endpoint was analysed using a stratified Cox proportional hazards model with treatment group (semaglutide, placebo) as fixed factor. Assuming the same population MACE risk for the semaglutide and placebo groups (i.e., the population HR equals 1), a total minimum of 122 events were needed in order to have at least 90% power to ascertain that the upper two-sided 95% confidence limit for the HR was less than 1.8.

Comparison groups	Semaglutide v Placebo
Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.0001 [1]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.95

Notes:

[1] - The 'p-value' is for the two-sided Wald test of non-inferiority with limit 1.8.

Statistical analysis title	Superiority

Statistical analysis description:

A post hoc analysis of superiority of semaglutide versus placebo was performed based on the pre-specified Cox proportional hazard analysis using the two-sided Wald test of no difference, with treatment (semaglutide, placebo) as fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo

Number of subjects included in analysis	3297
Analysis specification	Post-hoc
Analysis type	superiority
P-value	= 0.0167 [2]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.95

Notes:

[2] - The 'p-value' is for the two-sided Wald test of no difference.

Secondary: Time from randomisation to first occurrence of an expanded composite cardiovascular outcome.

End point title	Time from randomisation to first occurrence of an expanded composite cardiovascular outcome.

End point description:

Subjects experiencing first occurrence of an expanded composite CV outcome (defined as either MACE, revascularisation [coronary and peripheral], unstable angina requiring hospitalisation or hospitalisation for heart failure).

End point type	Secondary

End point timeframe:

Time from randomisation up to end of follow-up (scheduled at week 109)

End point values	Semaglutide	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1648	1649		
Units: proportion of subject				
number (not applicable)	12.1	16		

Statistical analyses

Statistical analysis title	Analysis for an expanded composite CV outcome

Statistical analysis description:

Analysis was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo

Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0016
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.89

Secondary: Time from randomisation to each individual component of the expanded composite cardiovascular outcome

End point title	Time from randomisation to each individual component of the expanded composite cardiovascular outcome

End point description:

Subjects experiencing an event onset for each individual component of the expanded composite cardiovascular outcomes (defined as either MACE, revascularisation [coronary and peripheral], unstable angina requiring hospitalisation or hospitalisation for heart failure).

End point type	Secondary

End point timeframe:

Time from randomisation up to end of Follow-up (scheduled at week 109)

End point values	Semaglutide	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1648	1649		
Units: proportion of subjects				
number (not applicable)				
Cardiovascular death	1.6	1.9		
Non-fatal MI	2.5	3.7		
Non-fatal Stroke	1.5	2.7		
Revascularisation	2.6	4.2		
UAP requiring hospitalisation	1.1	1.3		
Hospitalisation for heart failure	2.7	2.4		

Statistical analyses

Statistical analysis title	Analysis for cardiovascular death

Statistical analysis description:

Analysis for CV death was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo

Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9181
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.48

Statistical analysis title	Analysis for non-fatal myocardial infarction

Statistical analysis description:

Analysis for non-fatal myocardial infarction was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo
Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1194
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	1.08

Statistical analysis title	Analysis for non-fatal stroke

Statistical analysis description:

Analysis for non-fatal stroke was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo
Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0438
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.61

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.38
upper limit	0.99

Statistical analysis title	Analysis for revascularisation

Statistical analysis description:

Analysis for revascularisation was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo
Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0027
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	0.86

Statistical analysis title	Analysis for UA requiring hospitalisation

Statistical analysis description:

Analysis for 'unstable angina requiring hospitalisation' was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo
Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4914
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.47
upper limit	1.44

Statistical analysis title	Analysis for hospitalisation for heart failure

Statistical analysis description:

Analysis for hospitalisation for heart failure was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo
Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.5735
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.61

Secondary: Time from randomisation to first occurrence of all-cause death, non-fatal MI, or non-fatal stroke

End point title	Time from randomisation to first occurrence of all-cause death, non-fatal MI, or non-fatal stroke

End point description:

Proportion of subjects experiencing a first occurrence of all-cause death, non-fatal MI, or non-fatal stroke.

End point type	Secondary

End point timeframe:

Time from randomisation up to end of follow-up (scheduled at week 109)

End point values	Semaglutide	Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1648	1649		
Units: proportion of subjects				
number (not applicable)	7.4	9.6		

Statistical analyses

Statistical analysis title	Analysis

Statistical analysis description:

Analysis for all-cause death, non-fatal MI or non-fatal stroke was done by Cox proportional hazards model with treatment (semaglutide; placebo) as a fixed factor and stratified by all possible combinations of the three stratification factors used in the randomisation procedure (in total 9 levels).

Comparison groups	Semaglutide v Placebo

Number of subjects included in analysis	3297
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0292
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.97

Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: glycosylated haemoglobin (HbA1c)

End point title	Change from baseline to last assessment in the trial in other treatment outcomes: glycosylated haemoglobin (HbA1c)

End point description:

Estimated mean change from baseline in glycosylated haemoglobin (HbA1c) to last assessment in the trial during the treatment period.

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: percentage of glycosylated haemoglobin				
least squares mean (standard error)	-1.09 (± 0.05)	-1.41 (± 0.05)	-0.44 (± 0.05)	-0.36 (± 0.05)

Statistical analyses

Statistical analysis title	Analysis for HbA1c

Statistical analysis description:

Analysis was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-0.66

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	-0.52

Statistical analysis title	Analysis for HbA1c

Statistical analysis description:

Analysis was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.19
upper limit	-0.91

Secondary: Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: fasting plasma glucose

End point title	Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: fasting plasma glucose

End point description:

Estimated mean change from baseline to last assessment in fasting plasma glucose in the trial during the treatment period.

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: mg/dL				
least squares mean (standard error)	-1.75 (± 0.12)	-2.11 (± 0.12)	-1.02 (± 0.12)	-0.88 (± 0.12)

Statistical analyses

Statistical analysis title	Analysis for FPG

Statistical analysis description:

Analysis was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.06
upper limit	-0.38

Statistical analysis title	Analysis for FPG

Statistical analysis description:

Analysis was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.56
upper limit	-0.88

Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: body weight

End point title	Change from baseline to last assessment in the trial in other treatment outcomes: body weight[3]

End point description:

Estimated mean change from baseline to last assessment in body weight in the trial during the treatment period.

End point type	Secondary

End point timeframe:

Week 0, up to week 104

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The data for the two placebo arms are pooled for analysis and thus there are only 3 arms for this endpoint instead of four.

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	826	822	1649	
Units: kg				
least squares mean (standard error)	-3.57 (± 0.21)	-4.88 (± 0.22)	-0.62 (± 0.15)	

Statistical analyses

Statistical analysis title	Analysis for body weight

Statistical analysis description:

Analysis was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo
Number of subjects included in analysis	2475
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-2.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.47
upper limit	-2.44

Statistical analysis title	Analysis for body weight

Statistical analysis description:

Analysis was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo
Number of subjects included in analysis	2471
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	treatment difference
Point estimate	-4.27

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.78
upper limit	-3.75

Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: lipid profile

End point title	Change from baseline to last assessment in the trial in other treatment outcomes: lipid profile

End point description:

Estimated ratio to baseline at week 104 during the treatment period in lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides).

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: mg/dL				
least squares mean (standard error)				
Total cholesterol	0.97 (± 0.01)	0.97 (± 0.01)	1 (± 0.01)	0.99 (± 0.01)
HDL-Cholesterol	0.99 (± 0.01)	1.01 (± 0.01)	0.99 (± 0.01)	0.97 (± 0.01)
LDL-Cholesterol	0.97 (± 0.01)	0.98 (± 0.01)	1.01 (± 0.01)	0.99 (± 0.01)
Triglycerides	0.93 (± 0.01)	0.92 (± 0.01)	0.96 (± 0.01)	0.98 (± 0.01)

Statistical analyses

Statistical analysis title	Analysis for total cholesterol

Statistical analysis description:

Analysis for total cholesterol was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit. The response and its baseline value were log-transformed before analysis.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0149
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1

Statistical analysis title	Analysis for total cholesterol

Statistical analysis description:

Analysis for total cholesterol was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit. The response and its baseline value were log-transformed before analysis.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.258
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.01

Statistical analysis title	Analysis for HDL-cholesterol

Statistical analysis description:

Analysis for HDL-cholesterol was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.8106
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.02

Statistical analysis title	Analysis for HDL cholesterol

Statistical analysis description:

Analysis for HDL-cholesterol was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.99
upper limit	1.06

Statistical analysis title	Analysis for LDL-cholesterol

Statistical analysis description:

Analysis for LDL-cholesterol was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0185
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	0.99

Statistical analysis title	Analysis for LDL-cholesterol

Statistical analysis description:

Analysis for LDL-cholesterol was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg

Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.5996
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.96
upper limit	1.03

Statistical analysis title	Analysis for triglycerides

Statistical analysis description:

Analysis for triglycerides was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1833
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.01

Statistical analysis title	Analysis for triglycerides

Statistical analysis description:

Analysis for triglycerides was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0009
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	0.97

Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: lipid profile (free fatty acids)

End point title	Change from baseline to last assessment in the trial in other treatment outcomes: lipid profile (free fatty acids)

End point description:

Estimated mean change from baseline to last assessment in the trial during the treatment period in vital signs (pulse rate).

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: mmol/L				
least squares mean (standard error)	0.95 (± 0.02)	0.91 (± 0.01)	0.96 (± 0.02)	0.99 (± 0.02)

Statistical analyses

Statistical analysis title	Analysis for free fatty acids

Statistical analysis description:

Analysis for free fatty acids was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.7796
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.95
upper limit	1.04

Statistical analysis title	Analysis for free fatty acids

Statistical analysis description:

Analysis for free fatty acids was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0003
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	0.96

Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: urinary albumin to creatinine ratio

End point title	Change from baseline to last assessment in the trial in other treatment outcomes: urinary albumin to creatinine ratio

End point description:

Estimated ratio to baseline in urinary albumin to creatinine ratio at week 104 during the treatment period.

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: mg/g				
least squares mean (standard error)	1.02 (± 0.05)	0.91 (± 0.05)	1.32 (± 0.07)	1.29 (± 0.06)

Statistical analyses

Statistical analysis title	Analysis for urinary albumin to creatinine ratio

Statistical analysis description:

Analysis for urinary albumin to creatinine ration was donne using a mixed model for repeated

measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit. The response and its baseline value were log-transformed before analysis.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0003
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	0.89

Statistical analysis title	Analysis for urinary albumin to creatinine ratio

Statistical analysis description:

Analysis for urinary albumin to creatinine ration was donne using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit. The response and its baseline value were log-transformed before analysis.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.81

Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: vital signs

End point title	Change from baseline to last assessment in the trial in other treatment outcomes: vital signs

End point description:

Estimated mean change from baseline to last assessment in the trial during the treatment period in vital signs (diastolic blood pressure and systolic blood pressure).

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: mmHg				
least squares mean (standard error)				
Diastolic blood pressure (mmHg)	-1.37 (± 0.32)	-1.57 (± 0.32)	-1.42 (± 0.32)	-1.71 (± 0.32)
Systolic blood pressure (mmHg)	-3.44 (± 0.54)	-5.37 (± 0.54)	-2.17 (± 0.54)	-2.78 (± 0.54)

Statistical analyses

Statistical analysis title	Analysis for diastolic blood pressure

Statistical analysis description:

Analysis for diastolic blood pressure was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9205
Method	Mixed models analysis
Parameter estimate	Treatment ratio
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	0.92

Statistical analysis title	Analysis for diastolic blood pressure

Statistical analysis description:

Analysis for diastolic blood pressure was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.7477
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.14

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	1.03

Statistical analysis title	Analysis for systolic blood pressure

Statistical analysis description:

Analysis for systolic blood pressure was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0976
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.77
upper limit	0.23

Statistical analysis title	Analysis for systolic blood pressure

Statistical analysis description:

Analysis for systolic blood pressure was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0008
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-2.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.09
upper limit	-1.08

Secondary: Change from baseline to last assessment in the trial in other treatment

outcomes: vital signs (pulse rate)	
End point title	Change from baseline to last assessment in the trial in other treatment outcomes: vital signs (pulse rate)

End point description:

Estimated mean change from baseline to last assessment in the trial during the treatment period in vital signs (pulse rate).

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: beats/min				
least squares mean (standard error)	2.12 (± 0.34)	2.41 (± 0.34)	0.09 (± 0.34)	-0.07 (± 0.34)

Statistical analyses

Statistical analysis title	Analysis for pulse rate

Statistical analysis description:

Analysis for pulse rate was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	2.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	2.98

Statistical analysis title	Analysis for pulse rate

Statistical analysis description:

Analysis for pulse rate was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg

Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	2.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.52
upper limit	3.43

Secondary: Incidence during the trial in other treatment outcomes: hypoglycaemic events

End point title	Incidence during the trial in other treatment outcomes: hypoglycaemic events

End point description:

Rates (event rate per 100 exposure years) of severe or blood glucose confirmed symptomatic hypoglycaemia defned as an episode that was severe according to the ADA classification or BG confirmed by a PG value <3.1 mmol/L (56 mg/dL) with symptoms consistent with hypoglycaemia.

End point type	Secondary

End point timeframe:

Week 0 - 109

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: Event rate per 100 exposure years				
number (not applicable)	37.5	36.2	35.3	39.7

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence during the trial in other treatment outcomes: adverse events

End point title	Incidence during the trial in other treatment outcomes: adverse events

End point description:

Rates (event rate per 100 years of exposure) of treatment emergent adverse events during the treatment period (weeks 0-109)

End point type	Secondary

End point timeframe:

Weeks 0-109

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: Event rate per 100 years of exposure				
number (not applicable)	330.5	337	317.4	298.3

Statistical analyses

No statistical analyses for this end point

Secondary: Occurrence during the trial in other treatment outcomes: anti-semaglutide antibodies

End point title	Occurrence during the trial in other treatment outcomes: anti-semaglutide antibodies[4]

End point description:

The proportion of subjects that tested positive for anti-semaglutide antibodies at any time point post-baseline during the trial, from week 0 to week 109.

End point type	Secondary

End point timeframe:

Weeks 0-109

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: There will not be any antibody data for the two placebo arms. Thus the data is presented for only the 2 semaglutide arms for this endpoint.

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	826	822		
Units: proportion of subjects				
number (not applicable)	1.4	2.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to last assessment in the trial in other treatment outcomes: patient reported outcome (PRO)

End point title	Change from baseline to last assessment in the trial in other treatment outcomes: patient reported outcome (PRO)

End point description:

Estimated mean change from baseline to last assessment in the trial in patient reported outcomes (PRO). PRO questionnaire measured the individual overall health related quality of life namely bodily pain, general health, mental component summary, mental health, physical component summary,

physical functioning, role-emotional, role-physical, social functioning and vitality. The PRO scores were transformed to a 0−100 scale with higher scores indicating greater health related quality of life.

End point type	Secondary

End point timeframe:

Week 0, up to week 104

End point values	Semaglutide 0.5 mg	Semaglutide 1.0 mg	Placebo 0.5 mg	Placebo 1.0 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	826	822	824	825
Units: Score				
least squares mean (standard error)				
Bodily pain	0.66 (± 0.35)	1.82 (± 0.35)	0.16 (± 0.35)	0.35 (± 0.35)
General health	1.66 (± 0.29)	2.55 (± 0.29)	0.78 (± 0.29)	1.13 (± 0.3)
Mental component summary	0 (± 0.35)	0.86 (± 0.35)	-0.17 (± 0.35)	-0.11 (± 0.35)
Mental health	0.48 (± 0.33)	1.08 (± 0.33)	-0.14 (± 0.33)	-0.31 (± 0.33)
Physical component summary	0.76 (± 0.28)	1.74 (± 0.28)	0.07 (± 0.28)	0.35 (± 0.28)
Physical functioning	0.42 (± 0.32)	1.12 (± 0.32)	-0.38 (± 0.32)	-0.37 (± 0.33)
Role-emotional	0.17 (± 0.42)	0.89 (± 0.42)	-0.36 (± 0.42)	-0.05 (± 0.42)
Role-physical	0.39 (± 0.34)	1.18 (± 0.35)	-0.33 (± 0.35)	0.03 (± 0.35)
Social functioning	-0.25 (± 0.35)	0.97 (± 0.35)	-0.2 (± 0.36)	-0.17 (± 0.36)
Vitality	0.29 (± 0.31)	1.55 (± 0.31)	-0.04 (± 0.31)	0.35 (± 0.31)

Statistical analyses

Statistical analysis title	Analysis for bodily pain

Statistical analysis description:

Analysis for bodily pain was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.3171
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	1.47

Statistical analysis title	Analysis for bodily pain

Statistical analysis description:

Analysis for bodily pain was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0031
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	2.45

Statistical analysis title	Analysis for general health

Statistical analysis description:

Analysis for general health was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.035
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	1.69

Statistical analysis title	Analysis for general health

Statistical analysis description:

Analysis for general health was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg

Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0007
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	2.24

Statistical analysis title	Analysis for mental component summary

Statistical analysis description:

Analysis for mental component summary was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.7277
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.79
upper limit	1.13

Statistical analysis title	Analysis for mental component summary

Statistical analysis description:

Analysis for mental component summary was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0489
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	1.94

Statistical analysis title	Analysis for mental health

Statistical analysis description:

Analysis for mental health was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.186
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	1.53

Statistical analysis title	Analysis for mental health

Statistical analysis description:

Analysis for mental health was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0029
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	2.31

Statistical analysis title	Analysis for physical component summary

Statistical analysis description:

Analysis for physical component summary was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0833
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	1.45

Statistical analysis title	Analysis for physical component summary

Statistical analysis description:

Analysis for physical component summary was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0004
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	2.17

Statistical analysis title	Analysis for physical functioning

Statistical analysis description:

Analysis for physical functioning was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg

Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0799
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	1.69

Statistical analysis title	Analysis for physical functioning

Statistical analysis description:

Analysis for physical functioning was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0011
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	2.4

Statistical analysis title	Analysis for role emotional

Statistical analysis description:

Analysis for role emotional was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1431
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.53

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	1.68

Statistical analysis title	Analysis for role emotional

Statistical analysis description:

Analysis for role emotional was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1136
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	2.1

Statistical analysis title	Analysis for role physical

Statistical analysis description:

Analysis for role physical was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.1431
Method	Mixed models analysis
Parameter estimate	treatment difference
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	1.67

Statistical analysis title	Analysis for role physical

Statistical analysis description:

Analysis for role physical was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0197
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	2.11

Statistical analysis title	Analysis for social fuctioning

Statistical analysis description:

Analysis for social functioning was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.9223
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	0.93

Statistical analysis title	Analysis for social functioning

Statistical analysis description:

Analysis for social functioning was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg

Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0237
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	2.13

Statistical analysis title	Analysis for vitality

Statistical analysis description:

Analysis for vitality was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 0.5 mg v Placebo 0.5 mg
Number of subjects included in analysis	1650
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4523
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.53
upper limit	1.19

Statistical analysis title	Analysis for vitality

Statistical analysis description:

Analysis for vitality was done using a mixed model for repeated measurements with treatment (4 levels) and stratification (9 levels) as fixed factors and baseline value as covariate, all nested within visit.

Comparison groups	Semaglutide 1.0 mg v Placebo 1.0 mg
Number of subjects included in analysis	1647
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.0064
Method	Mixed models analysis
Parameter estimate	Treatment difference
Point estimate	1.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	2.07

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events from the first trial-related activity after the subject had signed the informed consent (week -2) until the end of the posttreatment follow-up period (week 109).

Adverse event reporting additional description:

Safety was assessed using the full analysis set which includes all randomised subjects. Subjects contribute to the evaluation as randomised.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18

Reporting groups

Reporting group title	Sema 0.5 mg
Reporting group description: -	
Reporting group title	Sema 1.0 mg
Reporting group description: -	
Reporting group title	Placebo 0.5 mg
Reporting group description: -	
Reporting group title	Placebo 1.0 mg
Reporting group description: -	

Serious adverse events	Sema 0.5 mg	Sema 1.0 mg	Placebo 0.5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	289 / 826 (34.99%)	276 / 822 (33.58%)	329 / 824 (39.93%)
number of deaths (all causes)	30	32	32
number of deaths resulting from adverse events	3	3	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute lymphocytic leukaemia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma gastric			

subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	0 / 824 (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
Adenocarcinoma of colon			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic astrocytoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell lymphoma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-cell small lymphocytic lymphoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign lymph node neoplasm			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 neoplasm of thyroid gland			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder papilloma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma recurrent			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma stage II			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Bone cancer metastatic			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Breast cancer			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Breast cancer in situ			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Breast cancer stage III			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cholesteatoma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondroma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Choroid melanoma			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 lymphocytic leukaemia			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon adenoma			
subjects affected / exposed	0 / 826 (0.00%)	4 / 822 (0.49%)	0 / 824 (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
Colon cancer			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon neoplasm			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial adenocarcinoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial sarcoma			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder adenocarcinoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Gastric cancer			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomus tumour			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Growth hormone-producing pituitary tumour			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 adenoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive breast carcinoma			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal squamous cell carcinoma			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma stage 0			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 adenocarcinoma stage IV			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 carcinoma cell type unspecified stage IV			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 neoplasm			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Lung neoplasm malignant			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant melanoma			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Metastases to liver			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Metastases to lung			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lymph nodes			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 gastric cancer			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Neoplasm of appendix			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Non-small cell lung cancer			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian epithelial cancer			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Ovarian germ cell teratoma benign			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma metastatic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pancreatic carcinoma stage IV			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 thyroid cancer			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraganglion neoplasm			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Parathyroid tumour benign			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phaeochromocytoma			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Plasma cell myeloma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	3 / 826 (0.36%)	3 / 822 (0.36%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer metastatic			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Prostate cancer recurrent			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage I			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage III			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer metastatic			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Renal cancer stage I			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 cell lung cancer			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 cancer metastatic			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Thyroid neoplasm			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric cancer			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 leiomyoma			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	0 / 824 (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
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	0 / 824 (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
Aortic dissection			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic stenosis			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial insufficiency			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 artery aneurysm			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Femoral artery occlusion			
subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	0 / 824 (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
Haematoma			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	3 / 826 (0.36%)	1 / 822 (0.12%)	0 / 824 (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
Hypertensive emergency			
subjects affected / exposed	4 / 826 (0.48%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 2
Intra-abdominal haematoma			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leriche syndrome			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Orthostatic hypotension			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	0 / 824 (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
Peripheral arterial occlusive disease			

subjects affected / exposed	3 / 826 (0.36%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 stenosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 thrombosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	2 / 824 (0.24%)
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 ischaemia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 vascular disorder			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock haemorrhagic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Temporal arteritis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose vein			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Vasculitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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			
Abdominal hernia repair			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Angioplasty			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachytherapy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid angioplasty			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stent insertion			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid endarterectomy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid revascularisation			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Cataract operation			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Coronary angioplasty			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary arterial stent insertion			
subjects affected / exposed	15 / 826 (1.82%)	8 / 822 (0.97%)	17 / 824 (2.06%)
occurrences causally related to treatment / all	1 / 19	1 / 9	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery bypass			
subjects affected / exposed	8 / 826 (0.97%)	5 / 822 (0.61%)	14 / 824 (1.70%)
occurrences causally related to treatment / all	0 / 8	0 / 5	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary revascularisation			
subjects affected / exposed	11 / 826 (1.33%)	10 / 822 (1.22%)	15 / 824 (1.82%)
occurrences causally related to treatment / all	0 / 12	0 / 10	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laparotomy			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ventilation			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal polypectomy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Percutaneous coronary intervention			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery angioplasty			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	0 / 824 (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
Peripheral artery bypass			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stent insertion			
subjects affected / exposed	1 / 826 (0.12%)	3 / 822 (0.36%)	0 / 824 (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
Peripheral endarterectomy			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 revascularisation			
subjects affected / exposed	2 / 826 (0.24%)	4 / 822 (0.49%)	5 / 824 (0.61%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pterygium operation			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Removal of internal fixation			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 artery stent placement			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Stent placement			
subjects affected / exposed	2 / 826 (0.24%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon sheath incision			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 repair			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 discomfort			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			

subjects affected / exposed	1 / 826 (0.12%)	3 / 822 (0.36%)	5 / 824 (0.61%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	2 / 826 (0.24%)	3 / 822 (0.36%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 3	0 / 3
Device malfunction			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug intolerance			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Gait disturbance			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Hyperthermia malignant			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Impaired healing			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metaplasia			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microlithiasis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Necrosis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	8 / 826 (0.97%)	5 / 822 (0.61%)	8 / 824 (0.97%)
occurrences causally related to treatment / all	1 / 8	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Oedema peripheral			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Sudden death			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 1
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Drug hypersensitivity			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoidosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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			
Benign prostatic hyperplasia			
subjects affected / exposed	3 / 826 (0.36%)	2 / 822 (0.24%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cyst			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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

Cystocele			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial hyperplasia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymal tenderness			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile dysfunction			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Genital haemorrhage			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Menorrhagia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic obstruction			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular cyst			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal prolapse			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acquired diaphragmatic eventration			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 pulmonary oedema			
subjects affected / exposed	3 / 826 (0.36%)	2 / 822 (0.24%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute respiratory failure			
subjects affected / exposed	3 / 826 (0.36%)	1 / 822 (0.12%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Asthma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Bronchospasm			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	3 / 826 (0.36%)	5 / 822 (0.61%)	7 / 824 (0.85%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 0
Dyspnoea			
subjects affected / exposed	6 / 826 (0.73%)	5 / 822 (0.61%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea at rest			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Haemoptysis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrothorax			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Hyperventilation			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Hypoxia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic pulmonary fibrosis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lung cyst			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Pleural effusion			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 826 (0.24%)	4 / 822 (0.49%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary mass			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 oedema			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory arrest			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	2 / 826 (0.24%)	3 / 822 (0.36%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Confusional state			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Homicidal ideation			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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	1 / 826 (0.12%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic stress disorder			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizoaffective disorder			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Sleep terror			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Arteriogram coronary			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial test positive			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose fluctuation			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood glucose increased			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	2 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood urea increased			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheterisation cardiac			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulation time prolonged			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ejection fraction decreased			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Electrocardiogram ST segment abnormal			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram change			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Pancreatic enzymes increased			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Transaminases increased			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin increased			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Injury, poisoning and procedural complications			
Accident at work			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Anaemia postoperative			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns third degree			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dural tear			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to anastomose			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	11 / 826 (1.33%)	5 / 822 (0.61%)	11 / 824 (1.33%)
occurrences causally related to treatment / all	0 / 11	0 / 5	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Foot fracture			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incorrect dose administered			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Injury			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Intentional overdose			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 vertebral fracture			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Muscle strain			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Near drowning			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Overdose			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative ileus			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
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 respiratory failure			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	2 / 826 (0.24%)	4 / 822 (0.49%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula fracture			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seroma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin abrasion			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Traumatic fracture			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic ulcer			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 graft complication			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 graft occlusion			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 pseudoaneurysm			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Wound			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 necrosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrong drug administered			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Congenital, familial and genetic disorders			
Phimosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	4 / 826 (0.48%)	3 / 822 (0.36%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	1 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute myocardial infarction			
subjects affected / exposed	16 / 826 (1.94%)	13 / 822 (1.58%)	15 / 824 (1.82%)
occurrences causally related to treatment / all	1 / 21	2 / 14	1 / 15
deaths causally related to treatment / all	1 / 5	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	9 / 826 (1.09%)	9 / 822 (1.09%)	16 / 824 (1.94%)
occurrences causally related to treatment / all	1 / 9	1 / 10	2 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	13 / 826 (1.57%)	15 / 822 (1.82%)	19 / 824 (2.31%)
occurrences causally related to treatment / all	0 / 16	0 / 18	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Aortic valve stenosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Arrhythmia			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	2 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	14 / 826 (1.69%)	12 / 822 (1.46%)	20 / 824 (2.43%)
occurrences causally related to treatment / all	1 / 16	2 / 15	4 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial thrombosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 / 826 (0.12%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrioventricular block first degree			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Atrioventricular block second degree			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyarrhythmia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Bundle branch block left			

subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	0 / 824 (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
Bundle branch block right			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 arrest			
subjects affected / exposed	5 / 826 (0.61%)	2 / 822 (0.24%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 3
Cardiac asthma			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Cardiac failure			
subjects affected / exposed	10 / 826 (1.21%)	10 / 822 (1.22%)	7 / 824 (0.85%)
occurrences causally related to treatment / all	0 / 11	2 / 10	0 / 9
deaths causally related to treatment / all	0 / 2	1 / 1	0 / 0
Cardiac failure acute			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Cardiac failure chronic			
subjects affected / exposed	8 / 826 (0.97%)	4 / 822 (0.49%)	6 / 824 (0.73%)
occurrences causally related to treatment / all	2 / 8	0 / 4	2 / 6
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	21 / 826 (2.54%)	14 / 822 (1.70%)	15 / 824 (1.82%)
occurrences causally related to treatment / all	2 / 31	0 / 17	0 / 19
deaths causally related to treatment / all	0 / 1	0 / 2	0 / 2
Cardiac tamponade			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Cardiogenic shock			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	1 / 3
Cardiomyopathy			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Cardiopulmonary failure			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiovascular insufficiency			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Congestive cardiomyopathy			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cor pulmonale acute			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	11 / 826 (1.33%)	9 / 822 (1.09%)	5 / 824 (0.61%)
occurrences causally related to treatment / all	1 / 11	1 / 9	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Coronary artery insufficiency			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 stenosis			
subjects affected / exposed	7 / 826 (0.85%)	2 / 822 (0.24%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic cardiomyopathy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular failure			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Mitral valve incompetence			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	4 / 826 (0.48%)	10 / 822 (1.22%)	9 / 824 (1.09%)
occurrences causally related to treatment / all	2 / 4	1 / 10	0 / 10
deaths causally related to treatment / all	0 / 1	1 / 3	0 / 1
Myocardial ischaemia			
subjects affected / exposed	6 / 826 (0.73%)	2 / 822 (0.24%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	1 / 6	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myocarditis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal arrhythmia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary valve stenosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Right ventricular failure			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Silent myocardial infarction			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Sinus node dysfunction			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Supraventricular extrasystoles			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Supraventricular tachycardia			
subjects affected / exposed	2 / 826 (0.24%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Tricuspid valve incompetence			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular asystole			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular hypokinesia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	1 / 826 (0.12%)	8 / 822 (0.97%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nervous system disorders			
Brain oedema			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem infarction			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Carotid artery occlusion			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery stenosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar haemorrhage			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar syndrome			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	2 / 826 (0.24%)	2 / 822 (0.24%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	1 / 2	1 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Cerebral ischaemia			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	3 / 826 (0.36%)	3 / 822 (0.36%)	6 / 824 (0.73%)
occurrences causally related to treatment / all	0 / 3	1 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cerebrovascular disorder			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical myelopathy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical radiculopathy			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Coma			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coordination abnormal			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cranial nerve disorder			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 mononeuropathy			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Headache			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Hepatic encephalopathy			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive encephalopathy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Hypoglycaemic coma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 unconsciousness			
subjects affected / exposed	5 / 826 (0.61%)	3 / 822 (0.36%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	2 / 5	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intracranial aneurysm			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial hypotension			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cerebral infarction			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	8 / 826 (0.97%)	7 / 822 (0.85%)	16 / 824 (1.94%)
occurrences causally related to treatment / all	2 / 8	3 / 8	0 / 16
deaths causally related to treatment / all	0 / 0	1 / 2	0 / 1
Lacunar infarction			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Metabolic encephalopathy			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Migraine			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Movement disorder			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis transverse			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Neuralgia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Parkinsonism			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Presyncope			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculitis lumbosacral			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	2 / 826 (0.24%)	4 / 822 (0.49%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 2	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalamic infarction			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	7 / 826 (0.85%)	6 / 822 (0.73%)	10 / 824 (1.21%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIIth nerve paralysis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve disorder			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 parkinsonism			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Visual field defect			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 826 (0.61%)	4 / 822 (0.49%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 5	0 / 4	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic anaemia			
subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Microcytic anaemia			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic vein thrombosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otosclerosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tympanic membrane perforation			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Amaurosis fugax			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
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 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract nuclear			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Cystoid macular oedema			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic retinopathy			
subjects affected / exposed	4 / 826 (0.48%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	1 / 4	0 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid dermatochalasis			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid ptosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glaucoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iridocyclitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular fibrosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular oedema			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Open angle glaucoma			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	0 / 824 (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 artery occlusion			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Retinal degeneration			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 detachment			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinopathy haemorrhagic			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous haemorrhage			
subjects affected / exposed	2 / 826 (0.24%)	2 / 822 (0.24%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal mass			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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			
subjects affected / exposed	2 / 826 (0.24%)	6 / 822 (0.73%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	1 / 2	2 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 pain upper			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Change of bowel habit			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Colitis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragmatic hernia			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	2 / 826 (0.24%)	6 / 822 (0.73%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	4 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Diverticulum intestinal			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Duodenitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 haemorrhagic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epigastric discomfort			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Faeces discoloured			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric disorder			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Gastric ileus			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polyps			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 ulcer haemorrhage			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	0 / 824 (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
Gastritis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Gastroduodenitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	5 / 826 (0.61%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal ischaemia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 826 (0.36%)	3 / 822 (0.36%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiatus hernia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Inguinal hernia			

subjects affected / exposed	4 / 826 (0.48%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal haemorrhage			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Intestinal obstruction			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal haemorrhage			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mouth ulceration			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 826 (0.00%)	3 / 822 (0.36%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal spasm			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic cyst			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumoperitoneum			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis haemorrhagic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal prolapse			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	0 / 824 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Volvulus of small bowel			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Vomiting			

subjects affected / exposed	0 / 826 (0.00%)	3 / 822 (0.36%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	2 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	3 / 826 (0.36%)	0 / 822 (0.00%)	6 / 824 (0.73%)
occurrences causally related to treatment / all	2 / 3	0 / 0	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis chronic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	4 / 826 (0.48%)	2 / 822 (0.24%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	1 / 4	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis obstructive			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder necrosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 polyp			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 cirrhosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 congestion			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocholecystis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Ischaemic hepatitis			

subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumobilia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Diabetic foot			
subjects affected / exposed	6 / 826 (0.73%)	2 / 822 (0.24%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 8	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Psoriasis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash papular			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin necrosis			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	3 / 826 (0.36%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	18 / 826 (2.18%)	6 / 822 (0.73%)	14 / 824 (1.70%)
occurrences causally related to treatment / all	1 / 22	3 / 8	2 / 14
deaths causally related to treatment / all	0 / 2	0 / 0	1 / 2
Acute prerenal failure			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anuria			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Azotaemia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder trabeculation			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	3 / 826 (0.36%)	3 / 822 (0.36%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic kidney disease			
subjects affected / exposed	10 / 826 (1.21%)	5 / 822 (0.61%)	14 / 824 (1.70%)
occurrences causally related to treatment / all	1 / 10	0 / 5	1 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Diabetic end stage renal disease			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis chronic			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Hydronephrosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Nephrolithiasis			
subjects affected / exposed	2 / 826 (0.24%)	3 / 822 (0.36%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Nephrotic syndrome			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Renal artery arteriosclerosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Renal colic			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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 failure			
subjects affected / exposed	2 / 826 (0.24%)	3 / 822 (0.36%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	3 / 826 (0.36%)	1 / 822 (0.12%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stag horn calculus			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder polyp			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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	2 / 826 (0.24%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthyroidism			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain			
subjects affected / exposed	1 / 826 (0.12%)	4 / 822 (0.49%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrolysis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 arthropathy			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 deformity			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc disorder			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			

subjects affected / exposed	3 / 826 (0.36%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mobility decreased			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Neck pain			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Osteoarthritis			

subjects affected / exposed	6 / 826 (0.73%)	8 / 822 (0.97%)	9 / 824 (1.09%)
occurrences causally related to treatment / all	0 / 7	0 / 8	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Rheumatoid arthritis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Soft tissue disorder			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 column stenosis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovial cyst			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal sepsis			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Abscess			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Acute hepatitis B			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergilloma			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Bacteraemia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Boutonneuse fever			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	2 / 826 (0.24%)	2 / 822 (0.24%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Bronchopneumonia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Campylobacter infection			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Cellulitis			
subjects affected / exposed	6 / 826 (0.73%)	3 / 822 (0.36%)	7 / 824 (0.85%)
occurrences causally related to treatment / all	0 / 6	1 / 3	0 / 7
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 foot infection			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 infectious			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterococcal infection			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Epididymitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	0 / 824 (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
Gangrene			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 826 (0.00%)	2 / 822 (0.24%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Implant site infection			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Infectious colitis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 / 826 (0.12%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labyrinthitis			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Necrotising fasciitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	5 / 826 (0.61%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 5	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Perirectal abscess			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Peritonsillar abscess			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Periumbilical abscess			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	1 / 826 (0.12%)	2 / 822 (0.24%)	0 / 824 (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
Pneumonia			
subjects affected / exposed	18 / 826 (2.18%)	15 / 822 (1.82%)	22 / 824 (2.67%)
occurrences causally related to treatment / all	2 / 19	0 / 16	0 / 26
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 1
Pneumonia pneumococcal			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
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 infection			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural pneumonia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 wound infection			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Pyelonephritis acute			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
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 chronic			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Respiratory tract infection viral			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	7 / 826 (0.85%)	4 / 822 (0.49%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	1 / 7	1 / 4	0 / 3
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 1
Septic encephalopathy			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Septic shock			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Sinusitis			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic abscess			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	2 / 826 (0.24%)	0 / 822 (0.00%)	0 / 824 (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
Staphylococcal osteomyelitis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Subcutaneous abscess			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Tuberculosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	9 / 826 (1.09%)	2 / 822 (0.24%)	10 / 824 (1.21%)
occurrences causally related to treatment / all	0 / 9	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection pseudomonal			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vestibular neuronitis			

subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	0 / 824 (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
Wound infection bacterial			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Dehydration			
subjects affected / exposed	3 / 826 (0.36%)	5 / 822 (0.61%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 3	1 / 5	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diabetes mellitus inadequate control			
subjects affected / exposed	4 / 826 (0.48%)	1 / 822 (0.12%)	5 / 824 (0.61%)
occurrences causally related to treatment / all	0 / 4	0 / 1	1 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	2 / 824 (0.24%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			

subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload			
subjects affected / exposed	2 / 826 (0.24%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Hyperglycaemia			
subjects affected / exposed	3 / 826 (0.36%)	2 / 822 (0.24%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	3 / 824 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hypocalcaemia			
subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	7 / 826 (0.85%)	2 / 822 (0.24%)	5 / 824 (0.61%)
occurrences causally related to treatment / all	5 / 8	1 / 2	5 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 826 (0.00%)	1 / 822 (0.12%)	0 / 824 (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
Hypomagnesaemia			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	0 / 824 (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
Hyponatraemia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	4 / 824 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	1 / 826 (0.12%)	0 / 822 (0.00%)	0 / 824 (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
Lactic acidosis			
subjects affected / exposed	1 / 826 (0.12%)	1 / 822 (0.12%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	0 / 824 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic disorder			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 826 (0.00%)	0 / 822 (0.00%)	1 / 824 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo 1.0 mg		
Total subjects affected by serious			

adverse events				
subjects affected / exposed	298 / 825 (36.12%)			
number of deaths (all causes)	28			
number of deaths resulting from adverse events	2			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute lymphocytic leukaemia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute myeloid leukaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma gastric				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma of colon				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Adenocarcinoma pancreas				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaplastic astrocytoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
B-cell lymphoma				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
B-cell small lymphocytic lymphoma				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal cell carcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign lymph node neoplasm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm of thyroid gland				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder neoplasm				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder papilloma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma recurrent				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bladder transitional cell carcinoma stage II				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone cancer metastatic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer in situ				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer stage III				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholangiocarcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholesteatoma				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chondroma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Choroid melanoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic lymphocytic leukaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clear cell renal cell carcinoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colon adenoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon cancer metastatic				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colon neoplasm				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colorectal cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial adenocarcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endometrial sarcoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Extranodal marginal zone B-cell lymphoma (MALT type)				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder adenocarcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glomus tumour				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Growth hormone-producing pituitary tumour				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic adenoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive breast carcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Invasive ductal breast carcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal squamous cell carcinoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lip neoplasm malignant stage unspecified				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma stage 0				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma stage IV				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung carcinoma cell type unspecified stage IV				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to bone				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to central nervous system				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to liver				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metastases to lung				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to lymph nodes				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic gastric cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasm of appendix				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian epithelial cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian germ cell teratoma benign				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma metastatic				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma stage IV				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papillary thyroid cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraganglion neoplasm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parathyroid tumour benign				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Phaeochromocytoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Plasma cell myeloma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostate cancer metastatic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer recurrent				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostate cancer stage I				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostate cancer stage III				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cancer metastatic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cancer stage I				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small cell lung cancer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of lung				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid cancer metastatic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid neoplasm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transitional cell carcinoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureteric cancer				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine leiomyoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Aortic aneurysm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic dissection				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic stenosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arterial insufficiency				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Circulatory collapse				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extremity necrosis				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femoral artery aneurysm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral artery occlusion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypertensive emergency				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Intra-abdominal haematoma				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leriche syndrome				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orthostatic hypotension				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Peripheral artery aneurysm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral artery thrombosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral vascular disorder				

subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Shock haemorrhagic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Temporal arteritis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicose vein				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vasculitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Abdominal hernia repair				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angioplasty				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brachytherapy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carotid angioplasty				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carotid artery stent insertion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carotid endarterectomy				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Carotid revascularisation				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cataract operation				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Coronary angioplasty				
subjects affected / exposed	5 / 825 (0.61%)			
occurrences causally related to treatment / all	1 / 5			
deaths causally related to treatment / all	0 / 0			
Coronary arterial stent insertion				
subjects affected / exposed	17 / 825 (2.06%)			
occurrences causally related to treatment / all	2 / 19			
deaths causally related to treatment / all	0 / 0			
Coronary artery bypass				
subjects affected / exposed	10 / 825 (1.21%)			
occurrences causally related to treatment / all	1 / 10			
deaths causally related to treatment / all	0 / 0			
Coronary revascularisation				

subjects affected / exposed	9 / 825 (1.09%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Hospitalisation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laparotomy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mechanical ventilation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasal polypectomy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Percutaneous coronary intervention				
subjects affected / exposed	6 / 825 (0.73%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Peripheral artery angioplasty				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Peripheral artery bypass				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stent insertion				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral endarterectomy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral revascularisation				
subjects affected / exposed	9 / 825 (1.09%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Pterygium operation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Removal of internal fixation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery stent placement				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stent placement				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tendon sheath incision				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia repair				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Chest discomfort				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Chest pain				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Device malfunction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug intolerance				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gait disturbance				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperthermia malignant				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired healing				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metaplasia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Microlithiasis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multi-organ failure				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Necrosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Oedema				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden cardiac death				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden death				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic shock				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug hypersensitivity				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sarcoidosis				

subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast cyst			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystocele			
subjects affected / exposed	1 / 825 (0.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endometrial hyperplasia			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epididymal tenderness			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erectile dysfunction			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Genital haemorrhage			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Menorrhagia			

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostatic obstruction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostatomegaly				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Testicular cyst				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine polyp				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaginal prolapse				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acquired diaphragmatic eventration				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute pulmonary oedema				

subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis chronic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	7 / 825 (0.85%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Dyspnoea at rest				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrothorax				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperventilation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Idiopathic pulmonary fibrosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal stenosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung cyst				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleurisy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary congestion				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			
Pulmonary hypertension				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pulmonary mass				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	5 / 825 (0.61%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Respiratory arrest				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Anxiety				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Depression				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Homicidal ideation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental status changes				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Post-traumatic stress disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Schizoaffective disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sleep terror				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Amylase increased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriogram coronary				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacterial test positive				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood glucose fluctuation				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood glucose increased				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood urea increased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Catheterisation cardiac				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coagulation time prolonged				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ejection fraction decreased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram ST segment abnormal				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram T wave inversion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocardiogram change				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lipase increased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test abnormal				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic enzymes increased				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transaminases increased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Troponin increased				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Weight decreased				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Accident at work				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alcohol poisoning				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia postoperative				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Animal bite				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burns third degree				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical vertebral fracture				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dural tear				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to anastomose				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	8 / 825 (0.97%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot fracture				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hand fracture				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incisional hernia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incorrect dose administered				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intentional overdose				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Laceration				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb injury				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar vertebral fracture				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meniscus injury				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscle strain				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Near drowning				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural haematoma				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Postoperative ileus				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative respiratory failure				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Scapula fracture				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Seroma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin abrasion				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thermal burn				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Traumatic fracture				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic haemothorax				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic ulcer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular graft complication				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular graft occlusion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular pseudoaneurysm				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound necrosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrong drug administered				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Phimosis				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute coronary syndrome				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Acute left ventricular failure				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Acute myocardial infarction				
subjects affected / exposed	27 / 825 (3.27%)			
occurrences causally related to treatment / all	2 / 28			
deaths causally related to treatment / all	0 / 2			
Angina pectoris				
subjects affected / exposed	12 / 825 (1.45%)			
occurrences causally related to treatment / all	2 / 12			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	22 / 825 (2.67%)			
occurrences causally related to treatment / all	0 / 23			
deaths causally related to treatment / all	0 / 0			
Aortic valve disease				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve stenosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				

subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	18 / 825 (2.18%)			
occurrences causally related to treatment / all	3 / 19			
deaths causally related to treatment / all	0 / 0			
Atrial flutter				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Atrial thrombosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Atrioventricular block first degree				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bradyarrhythmia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bundle branch block left				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Bundle branch block right				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	1 / 2			
Cardiac asthma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 1			
Cardiac failure acute				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cardiac failure chronic				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	18 / 825 (2.18%)			
occurrences causally related to treatment / all	1 / 21			
deaths causally related to treatment / all	0 / 1			
Cardiac tamponade				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac ventricular thrombosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cardiomyopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiopulmonary failure				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiovascular insufficiency				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congestive cardiomyopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cor pulmonale acute				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Coronary artery insufficiency				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery occlusion				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic cardiomyopathy				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertensive cardiomyopathy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic cardiomyopathy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Left ventricular failure				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Mitral valve incompetence				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	12 / 825 (1.45%)			
occurrences causally related to treatment / all	4 / 14			
deaths causally related to treatment / all	1 / 4			
Myocardial ischaemia				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Myocarditis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nodal arrhythmia				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary valve stenosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Right ventricular failure				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Silent myocardial infarction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus bradycardia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress cardiomyopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular extrasystoles				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tricuspid valve incompetence				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular arrhythmia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular asystole				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ventricular extrasystoles				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ventricular fibrillation				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 2			
Ventricular hypokinesia				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachyarrhythmia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Nervous system disorders				
Brain oedema				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brain stem infarction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carotid artery occlusion				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carotid artery stenosis				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Cerebellar haemorrhage				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebellar syndrome				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral ischaemia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Cerebrospinal fluid leakage				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	6 / 825 (0.73%)			
occurrences causally related to treatment / all	1 / 8			
deaths causally related to treatment / all	0 / 2			
Cerebrovascular disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical myelopathy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cervical radiculopathy				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic inflammatory demyelinating polyradiculoneuropathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coma				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coordination abnormal				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cranial nerve disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic mononeuropathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Embolic stroke				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epilepsy				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic stroke				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic encephalopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocephalus				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertensive encephalopathy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemic coma				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemic unconsciousness				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	2 / 6			
deaths causally related to treatment / all	0 / 0			
Hypoxic-ischaemic encephalopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intracranial aneurysm				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intracranial hypotension				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraventricular haemorrhage				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic cerebral infarction				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Lacunar infarction				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic encephalopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Movement disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple sclerosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelitis transverse				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuralgia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parkinsonism				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radiculitis lumbosacral				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radiculopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Speech disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Thalamic infarction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				

subjects affected / exposed	7 / 825 (0.85%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
VIIth nerve paralysis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
VIth nerve disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular parkinsonism				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Visual field defect				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic anaemia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphadenopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphadenopathy mediastinal				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Microcytic anaemia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Splenic vein thrombosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Splenomegaly				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Deafness neurosensory				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otosclerosis				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tympanic membrane perforation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vertigo				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Amaurosis fugax				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blindness				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cataract				
subjects affected / exposed	5 / 825 (0.61%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Cataract cortical				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cataract nuclear				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystoid macular oedema				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic retinopathy				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Diplopia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eyelid dermatochalasis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eyelid ptosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glaucoma				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Iridocyclitis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Macular fibrosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Macular oedema				

subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Open angle glaucoma			
subjects affected / exposed	1 / 825 (0.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal artery occlusion			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal degeneration			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	2 / 825 (0.24%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Retinopathy haemorrhagic			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitreous haemorrhage			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal mass			

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Abdominal pain lower				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Change of bowel habit				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic gastritis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis ischaemic				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Colitis ulcerative				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diaphragmatic hernia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer haemorrhage				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duodenitis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterocolitis haemorrhagic				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epigastric discomfort				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Faeces discoloured				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ileus				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric polyps				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer haemorrhage				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastritis haemorrhagic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroduodenitis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal ischaemia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haematemesis				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiatus hernia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired gastric emptying				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal haemorrhage				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Intestinal ischaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal perforation				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestinal haemorrhage				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine polyp				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mouth ulceration				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Oesophageal spasm				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic cyst				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				

subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	2 / 4			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritoneal haemorrhage				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumoperitoneum				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Proctitis haemorrhagic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal prolapse				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				

subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Volvulus of small bowel				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Bile duct stone				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Biliary colic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholangitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Cholecystitis acute				

subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Cholecystitis chronic				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis obstructive				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholestasis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder necrosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder polyp				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic cirrhosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic congestion				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocholecystis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic hepatitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumobilia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Actinic keratosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angioedema				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Decubitus ulcer				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic foot				
subjects affected / exposed	5 / 825 (0.61%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Hyperkeratosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pruritus				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psoriasis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash papular				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin necrosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin ulcer				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Stevens-Johnson syndrome				

subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	22 / 825 (2.67%)		
occurrences causally related to treatment / all	5 / 24		
deaths causally related to treatment / all	0 / 2		
Acute prerenal failure			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anuria			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Azotaemia			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder trabeculation			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus ureteric			
subjects affected / exposed	1 / 825 (0.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	1 / 825 (0.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic kidney disease			

subjects affected / exposed	5 / 825 (0.61%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Diabetic end stage renal disease				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysuria				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glomerulonephritis chronic				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Nephropathy				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephrotic syndrome				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Proteinuria				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery arteriosclerosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery stenosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal colic				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal cyst				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal failure				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal impairment				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Stag horn calculus				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethral stenosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary bladder polyp				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary incontinence				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Goitre				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperthyroidism				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inappropriate antidiuretic hormone secretion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid mass				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Arthritis				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	6 / 825 (0.73%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Chondrolysis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Costochondritis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic arthropathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibromyalgia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot deformity				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mobility decreased				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscle spasms				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				

subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neck pain				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	10 / 825 (1.21%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rheumatoid arthritis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft tissue disorder				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal column stenosis				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Synovial cyst				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abdominal sepsis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute hepatitis B				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Aspergilloma				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Boutonneuse fever				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchitis bacterial				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Campylobacter gastroenteritis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Campylobacter infection				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	9 / 825 (1.09%)			
occurrences causally related to treatment / all	0 / 10			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dengue fever				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic foot infection				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis infectious				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterococcal infection				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epididymitis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia infection				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastritis viral				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Gastroenteritis rotavirus				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis salmonella				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Implant site infection				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incision site infection				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infectious colitis				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infective exacerbation of chronic obstructive airways disease				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Labyrinthitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngitis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Liver abscess				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lobar pneumonia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis bacterial				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Necrotising fasciitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Otitis externa				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paronychia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perirectal abscess				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peritonsillar abscess				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Periumbilical abscess				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	14 / 825 (1.70%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 1			
Pneumonia pneumococcal				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post procedural pneumonia				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pseudomembranous colitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis chronic				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	7 / 825 (0.85%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 1			
Septic encephalopathy				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	3 / 825 (0.36%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 3			
Sinusitis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Soft tissue infection				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Splenic abscess				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal osteomyelitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Subcutaneous abscess				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth abscess				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tuberculosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	6 / 825 (0.73%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection pseudomonal				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection staphylococcal				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Urosepsis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vestibular neuronitis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection bacterial				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Acidosis				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				

subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus inadequate control				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Failure to thrive				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Fluid overload				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gout				
subjects affected / exposed	2 / 825 (0.24%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	4 / 825 (0.48%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				

subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	6 / 825 (0.73%)			
occurrences causally related to treatment / all	4 / 6			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypomagnesaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	0 / 825 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lactic acidosis				
subjects affected / exposed	1 / 825 (0.12%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				

subjects affected / exposed	1 / 825 (0.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolic disorder			
subjects affected / exposed	0 / 825 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obesity			
subjects affected / exposed	1 / 825 (0.12%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Sema 0.5 mg	Sema 1.0 mg	Placebo 0.5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	573 / 826 (69.37%)	587 / 822 (71.41%)	547 / 824 (66.38%)
Investigations			
Amylase increased			
subjects affected / exposed	31 / 826 (3.75%)	48 / 822 (5.84%)	28 / 824 (3.40%)
occurrences (all)	39	57	33
Lipase increased			
subjects affected / exposed	94 / 826 (11.38%)	90 / 822 (10.95%)	66 / 824 (8.01%)
occurrences (all)	121	123	76
Nervous system disorders			
Dizziness			
subjects affected / exposed	53 / 826 (6.42%)	46 / 822 (5.60%)	38 / 824 (4.61%)
occurrences (all)	57	54	53
Headache			
subjects affected / exposed	54 / 826 (6.54%)	58 / 822 (7.06%)	67 / 824 (8.13%)
occurrences (all)	77	89	114
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	41 / 826 (4.96%)	33 / 822 (4.01%)	44 / 824 (5.34%)
occurrences (all)	46	34	46
General disorders and administration			

site conditions			
Fatigue			
subjects affected / exposed	24 / 826 (2.91%)	42 / 822 (5.11%)	15 / 824 (1.82%)
occurrences (all)	27	48	16
Eye disorders			
Cataract			
subjects affected / exposed	55 / 826 (6.66%)	43 / 822 (5.23%)	37 / 824 (4.49%)
occurrences (all)	59	48	38
Diabetic retinopathy			
subjects affected / exposed	46 / 826 (5.57%)	56 / 822 (6.81%)	39 / 824 (4.73%)
occurrences (all)	50	63	39
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	45 / 826 (5.45%)	35 / 822 (4.26%)	33 / 824 (4.00%)
occurrences (all)	54	40	37
Abdominal pain upper			
subjects affected / exposed	35 / 826 (4.24%)	42 / 822 (5.11%)	19 / 824 (2.31%)
occurrences (all)	37	53	22
Constipation			
subjects affected / exposed	46 / 826 (5.57%)	79 / 822 (9.61%)	37 / 824 (4.49%)
occurrences (all)	52	97	42
Diarrhoea			
subjects affected / exposed	148 / 826 (17.92%)	148 / 822 (18.00%)	97 / 824 (11.77%)
occurrences (all)	277	245	159
Dyspepsia			
subjects affected / exposed	51 / 826 (6.17%)	63 / 822 (7.66%)	23 / 824 (2.79%)
occurrences (all)	68	88	25
Nausea			
subjects affected / exposed	143 / 826 (17.31%)	179 / 822 (21.78%)	62 / 824 (7.52%)
occurrences (all)	233	282	78
Vomiting			
subjects affected / exposed	87 / 826 (10.53%)	122 / 822 (14.84%)	42 / 824 (5.10%)
occurrences (all)	128	170	51
Respiratory, thoracic and mediastinal disorders			
Cough			

subjects affected / exposed	36 / 826 (4.36%)	32 / 822 (3.89%)	40 / 824 (4.85%)
occurrences (all)	41	33	41
Renal and urinary disorders			
Microalbuminuria			
subjects affected / exposed	27 / 826 (3.27%)	33 / 822 (4.01%)	46 / 824 (5.58%)
occurrences (all)	30	35	51
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	41 / 826 (4.96%)	35 / 822 (4.26%)	57 / 824 (6.92%)
occurrences (all)	45	40	69
Back pain			
subjects affected / exposed	54 / 826 (6.54%)	49 / 822 (5.96%)	49 / 824 (5.95%)
occurrences (all)	54	58	59
Pain in extremity			
subjects affected / exposed	38 / 826 (4.60%)	29 / 822 (3.53%)	46 / 824 (5.58%)
occurrences (all)	42	31	51
Infections and infestations			
Bronchitis			
subjects affected / exposed	46 / 826 (5.57%)	38 / 822 (4.62%)	49 / 824 (5.95%)
occurrences (all)	52	43	52
Influenza			
subjects affected / exposed	51 / 826 (6.17%)	48 / 822 (5.84%)	48 / 824 (5.83%)
occurrences (all)	60	56	57
Nasopharyngitis			
subjects affected / exposed	66 / 826 (7.99%)	60 / 822 (7.30%)	78 / 824 (9.47%)
occurrences (all)	91	77	99
Upper respiratory tract infection			
subjects affected / exposed	53 / 826 (6.42%)	51 / 822 (6.20%)	63 / 824 (7.65%)
occurrences (all)	59	64	75
Urinary tract infection			
subjects affected / exposed	78 / 826 (9.44%)	71 / 822 (8.64%)	64 / 824 (7.77%)
occurrences (all)	108	93	97
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	86 / 826 (10.41%)	75 / 822 (9.12%)	19 / 824 (2.31%)
occurrences (all)	97	88	21

Non-serious adverse events	Placebo 1.0 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	524 / 825 (63.52%)		
Investigations			
Amylase increased			
subjects affected / exposed	28 / 825 (3.39%)		
occurrences (all)	33		
Lipase increased			
subjects affected / exposed	69 / 825 (8.36%)		
occurrences (all)	83		
Nervous system disorders			
Dizziness			
subjects affected / exposed	38 / 825 (4.61%)		
occurrences (all)	45		
Headache			
subjects affected / exposed	74 / 825 (8.97%)		
occurrences (all)	110		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	48 / 825 (5.82%)		
occurrences (all)	55		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	26 / 825 (3.15%)		
occurrences (all)	28		
Eye disorders			
Cataract			
subjects affected / exposed	45 / 825 (5.45%)		
occurrences (all)	46		
Diabetic retinopathy			
subjects affected / exposed	38 / 825 (4.61%)		
occurrences (all)	43		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	31 / 825 (3.76%)		
occurrences (all)	36		
Abdominal pain upper			

subjects affected / exposed	19 / 825 (2.30%)		
occurrences (all)	33		
Constipation			
subjects affected / exposed	36 / 825 (4.36%)		
occurrences (all)	38		
Diarrhoea			
subjects affected / exposed	87 / 825 (10.55%)		
occurrences (all)	112		
Dyspepsia			
subjects affected / exposed	18 / 825 (2.18%)		
occurrences (all)	19		
Nausea			
subjects affected / exposed	66 / 825 (8.00%)		
occurrences (all)	94		
Vomiting			
subjects affected / exposed	33 / 825 (4.00%)		
occurrences (all)	41		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	46 / 825 (5.58%)		
occurrences (all)	48		
Renal and urinary disorders			
Microalbuminuria			
subjects affected / exposed	42 / 825 (5.09%)		
occurrences (all)	45		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	58 / 825 (7.03%)		
occurrences (all)	70		
Back pain			
subjects affected / exposed	48 / 825 (5.82%)		
occurrences (all)	50		
Pain in extremity			
subjects affected / exposed	42 / 825 (5.09%)		
occurrences (all)	45		
Infections and infestations			

Bronchitis subjects affected / exposed occurrences (all)	51 / 825 (6.18%) 64		
Influenza subjects affected / exposed occurrences (all)	46 / 825 (5.58%) 63		
Nasopharyngitis subjects affected / exposed occurrences (all)	66 / 825 (8.00%) 84		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	65 / 825 (7.88%) 88		
Urinary tract infection subjects affected / exposed occurrences (all)	68 / 825 (8.24%) 87		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	9 / 825 (1.09%) 10		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 May 2013	To accommodate a request from FDA and changes in FDA requirements to the primary objective, the statistical section and other relevant sections were updated accordingly. Additional minor updates were made.
18 June 2014	The definition of hypoglycaemia was updated including related endpoints, associated statistical analysis and how to report. Additional minor updates for clarification.

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/27633186