



## Clinical trial results:

### **A Randomized, Multicenter, Double-Blind, Parallel, Placebo-Controlled Study of the Effects of JNJ 28431754 on Cardiovascular Outcomes in Adult Subjects With Type 2 Diabetes Mellitus**

#### **Summary**

EudraCT number	2009-012140-16
Trial protocol	GB DE ES HU EE CZ SE BE
Global end of trial date	22 February 2017

#### **Results information**

Result version number	v1 (current)
This version publication date	10 March 2018
First version publication date	10 March 2018

#### **Trial information**

##### **Trial identification**

Sponsor protocol code	28431754DIA3008
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##### **Additional study identifiers**

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01032629
WHO universal trial number (UTN)	-

Notes:

##### **Sponsors**

Sponsor organisation name	Janssen- Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry group, Janssen- Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry group, Janssen- Cilag International NV, ClinicalTrialsEU@its.jnj.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	22 February 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 February 2017
Global end of trial reached?	Yes
Global end of trial date	22 February 2017
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this study was to assess the effect of canagliflozin plus standard of care relative to placebo plus standard of care on cardiovascular (CV) risk as measured by the hazard ratio (HR) for a composite endpoint (major adverse cardiovascular events [MACE] including CV death, nonfatal myocardial infarction [MI], or nonfatal stroke) and to assess the safety and tolerability of canagliflozin plus standard of care relative to placebo plus standard of care. Furthermore, study DIA3008 together with study DIA4003, constitutes the CANVAS program. An integrated analysis of CANVAS for cardiovascular safety was to use all subjects in DIA3008 and DIA4003 to show that a canagliflozin-associated risk in the CV risk ratio (if any), was significantly less than 1.3 using the two-sided 95 percent (%) confidence interval of the risk ratio.

Protection of trial subjects:

Safety was evaluated based on the following variables: adverse events, safety laboratory tests (hematology, serum chemistry, urinalysis), hypoglycemic episodes (as collected in a specific electronic case report forms [eCRF]), vital sign measurements (blood pressure and pulse rate), and 12-lead electrocardiograms (ECGs). Several monitoring and adjudication committees were commissioned for this study, including an Academic Research Organization (ARO) which provided scientific and academic oversight and site monitoring for some sites; a Steering Committee of external scientific experts; an Independent Data Monitoring Committee (IDMC); an independent Endpoint Adjudication Committee (EAC), which reviewed blinded data for selected specific events; separate adjudication committees, which were employed to review cases of diabetic ketoacidosis (DKA), fracture, renal events, and pancreatitis; and a company-internal Medical Safety Review Committee (MSRC).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 November 2009
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: 160
Country: Number of subjects enrolled	Australia: 177
Country: Number of subjects enrolled	Belgium: 21
Country: Number of subjects enrolled	Canada: 396
Country: Number of subjects enrolled	Colombia: 7
Country: Number of subjects enrolled	Czech Republic: 117
Country: Number of subjects enrolled	Germany: 175
Country: Number of subjects enrolled	Spain: 209
Country: Number of subjects enrolled	Estonia: 44
Country: Number of subjects enrolled	United Kingdom: 92

Country: Number of subjects enrolled	Hungary: 125
Country: Number of subjects enrolled	India: 695
Country: Number of subjects enrolled	Israel: 25
Country: Number of subjects enrolled	Luxembourg: 1
Country: Number of subjects enrolled	Mexico: 124
Country: Number of subjects enrolled	Malaysia: 73
Country: Number of subjects enrolled	Netherlands: 228
Country: Number of subjects enrolled	Norway: 109
Country: Number of subjects enrolled	New Zealand: 74
Country: Number of subjects enrolled	Poland: 144
Country: Number of subjects enrolled	Russian Federation: 389
Country: Number of subjects enrolled	Sweden: 71
Country: Number of subjects enrolled	Ukraine: 147
Country: Number of subjects enrolled	United States: 727
Worldwide total number of subjects	4330
EEA total number of subjects	1336

Notes:

<b>Subjects enrolled per age group</b>	
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)	2602
From 65 to 84 years	1723
85 years and over	5

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Out of 7693 subjects screened, a total of 4,330 subjects were randomized, with 1,442, 1,445, and 1,443 subjects assigned to placebo, canagliflozin 100 milligram (mg) and canagliflozin 300 mg respectively.

### Period 1

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

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Placebo

Arm description:

Subjects received one placebo capsule orally once daily for the duration of the study or until early discontinuation from treatment.

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

Dosage and administration details:

Subjects received one placebo capsule orally once daily for the duration of the study or until early discontinuation from treatment.

<b>Arm title</b>	Canagliflozin 100 mg
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Arm description:

Subjects received one canagliflozin 100 mg capsule once daily for the duration of the study or until early discontinuation from treatment.

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

Dosage and administration details:

Subjects received one canagliflozin 100 mg capsule once daily for the duration of the study or until early discontinuation from treatment.

<b>Arm title</b>	Canagliflozin 300 mg
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Arm description:

Subjects received one canagliflozin 300 mg capsule once daily for the duration of the study or until early discontinuation from treatment.

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

Dosage and administration details:

Subjects received one canagliflozin 300 mg capsule once daily for the duration of the study or until early discontinuation from treatment.

<b>Number of subjects in period 1</b>	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Started	1442	1445	1443
Completed	1297	1344	1355
Not completed	145	101	88
Consent withdrawn by subject	50	36	35
Other - closed site	21	18	16
Lost to follow-up	74	47	37

## Baseline characteristics

### Reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received one placebo capsule orally once daily for the duration of the study or until early discontinuation from treatment.	
Reporting group title	Canagliflozin 100 mg
Reporting group description: Subjects received one canagliflozin 100 mg capsule once daily for the duration of the study or until early discontinuation from treatment.	
Reporting group title	Canagliflozin 300 mg
Reporting group description: Subjects received one canagliflozin 300 mg capsule once daily for the duration of the study or until early discontinuation from treatment.	

Reporting group values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Number of subjects	1442	1445	1443
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	890	874	838
From 65 to 84 years	549	571	603
85 years and over	3	0	2
Title for AgeContinuous Units: years			
arithmetic mean	62.3	62.2	62.8
standard deviation	± 7.94	± 8	± 8.13
Title for Gender Units: subjects			
Female	486	484	499
Male	956	961	944

Reporting group values	Total		
Number of subjects	4330		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	2602		
From 65 to 84 years	1723		
85 years and over	5		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		

Title for Gender			
Units: subjects			
Female	1469		
Male	2861		

## End points

### End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received one placebo capsule orally once daily for the duration of the study or until early discontinuation from treatment.	
Reporting group title	Canagliflozin 100 mg
Reporting group description: Subjects received one canagliflozin 100 mg capsule once daily for the duration of the study or until early discontinuation from treatment.	
Reporting group title	Canagliflozin 300 mg
Reporting group description: Subjects received one canagliflozin 300 mg capsule once daily for the duration of the study or until early discontinuation from treatment.	
Subject analysis set title	Canagliflozin (Total)
Subject analysis set type	Intention-to-treat
Subject analysis set description: Subjects received one canagliflozin 100 mg or 300 mg capsule once daily for the duration of the study or until early discontinuation from treatment.	

### Primary: Time to the First Occurrence of Major Adverse Cardiovascular Events (MACE), Including CV Death, Non-Fatal Myocardial Infarction (MI), and Non-Fatal Stroke

End point title	Time to the First Occurrence of Major Adverse Cardiovascular Events (MACE), Including CV Death, Non-Fatal Myocardial Infarction (MI), and Non-Fatal Stroke
End point description: Time to the first occurrence of Major Adverse Cardiovascular Events (MACE), defined as a composite of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke. Adjudication of these events by the Endpoint Adjudication Committee (EAC) was performed in a blinded fashion. The primary analysis was based on the intent-to-treat (ITT) analysis set for adjudicated MACE, and included all randomized subjects. Event rate estimated based on the time to the first occurrence of MACE are presented.	
End point type	Primary
End point timeframe: Up to approximately 8 years	

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	Canagliflozin (Total)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1442	1445	1443	2888
Units: Events per 1000 patient-year				
number (not applicable)	30.36	28.41	25.37	26.89

### Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	



Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2887
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4576
Method	Cox proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.12

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2885
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0467
Method	Cox proportional hazard model
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1

<b>Statistical analysis title</b>	Statistical analysis 3
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin (Total)
Number of subjects included in analysis	4330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.112
Method	Cox proportional hazard method
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.03

## Secondary: Change from Baseline in Homeostasis Model Assessment 2 Steady-state Beta-Cell Function (HOMA2-%B) at the end-of-Treatment (EOT)

End point title	Change from Baseline in Homeostasis Model Assessment 2 Steady-state Beta-Cell Function (HOMA2-%B) at the end-of-Treatment (EOT)
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### End point description:

The homeostatic model assessment (HOMA) quantifies insulin resistance and beta-cell function. HOMA2-%B is a computer model that uses fasting plasma insulin and glucose concentrations to estimate steady-state beta cell function (%B) as a percentage of a normal reference population (normal young adults). The normal reference population was set at 100 percent. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and any post-baseline HOMA-B measurements, and didn't receive insulin through baseline.

End point type	Secondary
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### End point timeframe:

Baseline, and end of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	463	511	477	
Units: Beta cell function				
least squares mean (standard error)	4.02 (± 1.611)	6.82 (± 1.533)	8.09 (± 1.587)	

## Statistical analyses

Statistical analysis title	Statistical analysis 1
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### Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	974
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.21
Method	ANCOVA
Parameter estimate	Difference of Least Square Mean
Point estimate	2.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.571
upper limit	7.154
Variability estimate	Standard error of the mean
Dispersion value	2.224

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	940
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.072
Method	ANCOVA
Parameter estimate	Difference of Least Square Mean
Point estimate	4.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.368
upper limit	8.504
Variability estimate	Standard error of the mean
Dispersion value	2.261

## Secondary: Percentage of Subjects With Progression of Albuminuria at the end-of-Treatment

End point title	Percentage of Subjects With Progression of Albuminuria at the end-of-Treatment
End point description: Progression defined as the development of micro-albuminuria (ACR greater than or equal to [ $\geq$ ] 30 mg/g and smaller than or equal to $\leq$ 300 mg/g) or macroalbuminuria (ACR of $>300$ mg/g) in a subject with baseline normoalbuminuria or the development of macro-albuminuria in a subject with baseline microalbuminuria. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were treated, had both baseline and post-baseline ACR measurements, and baseline ACR $\leq 300$ mg/g.	
End point type	Secondary
End point timeframe: End of treatment (approximately maximum 338 weeks)	

<b>End point values</b>	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1286	1334	1298	
Units: Percentage of subjects				
number (not applicable)	24.0	20.2	18.3	

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2620
Analysis specification	Pre-specified
Analysis type	superiority
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	0.97

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2584
Analysis specification	Pre-specified
Analysis type	superiority
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.85

## Secondary: Change from Baseline in Proinsulin/Insulin Ratio at the end-of-Treatment

End point title	Change from Baseline in Proinsulin/Insulin Ratio at the end-of-Treatment
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**End point description:**

A raised proinsulin-to-insulin ratio due to impaired processing of proinsulin is an early marker of beta cell dysfunction. Beta-cell dysfunction was evaluated by calculating the PI/I ratio, which estimates the capacity of beta cells to convert proinsulin to insulin and may represent an acceptable method to indicate the degree of beta-cell secretion. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and any post-baseline proinsulin/insulin ratio measurements, and didn't receive insulin through baseline.

End point type	Secondary
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**End point timeframe:**

Baseline and end of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	370	426	412	
Units: Picomole per milli international units				
least squares mean (standard error)	0.70 (± 0.150)	0.67 (± 0.140)	1.03 (± 0.142)	

**Statistical analyses**

<b>Statistical analysis title</b>	Statistical analysis 1
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**Statistical analysis description:**

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	796
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.429
upper limit	0.374
Variability estimate	Standard error of the mean
Dispersion value	0.205

<b>Statistical analysis title</b>	Statistical analysis 2
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**Statistical analysis description:**

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 300 mg
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Number of subjects included in analysis	782
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.079
upper limit	0.731
Variability estimate	Standard error of the mean
Dispersion value	0.206

## Secondary: Change From Baseline in Urinary Albumin/Creatinine Ratio at end-of-Treatment

End point title	Change From Baseline in Urinary Albumin/Creatinine Ratio at end-of-Treatment
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End point description:

Urinary Albumin/Creatinine Ratio was reported at end of Treatment. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint and had both baseline and post-baseline ACR measurements.

End point type	Secondary
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End point timeframe:

End of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1377	1398	1384	
Units: Milligram per gram (mg/g)				
geometric mean (confidence interval 95%)	29.30 (27.66 to 31.03)	25.50 (24.09 to 27)	24.47 (23.11 to 25.91)	

## Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
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Number of subjects included in analysis	2775
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	0.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	0.94

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2761
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	0.91

## **Secondary: Change From Baseline in Estimated Glomerular Filtration Rate (eGFR) at end-of-Treatment**

End point title	Change From Baseline in Estimated Glomerular Filtration Rate (eGFR) at end-of-Treatment
End point description:	
Change From Baseline in Estimated Glomerular Filtration Rate (eGFR) was assessed at end of Treatment. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and post-baseline eGFR measurements.	
End point type	Secondary
End point timeframe:	
Baseline, end of treatment (approximately maximum 338 weeks)	

<b>End point values</b>	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1394	1412	1383	
Units: Milliliter/minute/1.73* <sup>2</sup> square meter				
least squares mean (standard error)	-5.23 (± 0.390)	-3.55 (± 0.388)	-3.98 (± 0.392)	

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis 1
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2806
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	1.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.599
upper limit	2.755
Variability estimate	Standard error of the mean
Dispersion value	0.55

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2777
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	2.328
Variability estimate	Standard error of the mean
Dispersion value	0.553



**Secondary: Change From Baseline in Glycated Hemoglobin (HbA1c) at end-of-Treatment**

End point title	Change From Baseline in Glycated Hemoglobin (HbA1c) at end-of-Treatment
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End point description:

Change from baseline in Glycated Hemoglobin (HbA1c) was assessed at end of Treatment. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and any post-baseline HbA1C measurements.

End point type	Secondary
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End point timeframe:

Baseline and end of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1366	1392	1352	
Units: Percentage of HbA1c				
least squares mean (standard error)	0.01 ( $\pm$ 0.032)	-0.26 ( $\pm$ 0.032)	-0.31 ( $\pm$ 0.032)	

**Statistical analyses**

<b>Statistical analysis title</b>	Statistical analysis 1
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2758
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-0.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.355
upper limit	-0.177
Variability estimate	Standard error of the mean
Dispersion value	0.045

<b>Statistical analysis title</b>	Statistical analysis 2
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 300 mg
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Number of subjects included in analysis	2718
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.405
upper limit	-0.227
Variability estimate	Standard error of the mean
Dispersion value	0.046

## Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) Levels at end-of-Treatment

End point title	Change From Baseline in Fasting Plasma Glucose (FPG) Levels at end-of-Treatment
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End point description:

Change from baseline in the fasting plasma glucose was assessed. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint and had both baseline and post-baseline fasting plasma glucose measurements.

End point type	Secondary
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End point timeframe:

Baseline and end of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1392	1410	1377	
Units: Millimoles per liter (mmol/L)				
least squares mean (standard error)	0.16 (± 0.076)	-0.42 (± 0.075)	-0.57 (± 0.076)	

## Statistical analyses

Statistical analysis title	Statistical analysis 1
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
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Number of subjects included in analysis	2802
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.794
upper limit	-0.374
Variability estimate	Standard error of the mean
Dispersion value	0.107

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2769
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.945
upper limit	-0.523
Variability estimate	Standard error of the mean
Dispersion value	0.108

<b>Secondary: Percent Change From Baseline in Body Weight at end-of-Treatment</b>	
End point title	Percent Change From Baseline in Body Weight at end-of-Treatment
End point description: Percent change from baseline in body weight was assessed at the end of treatment. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and post-baseline body weight.	
End point type	Secondary
End point timeframe: Baseline and end of treatment (approximately maximum 338 weeks)	

<b>End point values</b>	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1398	1415	1388	
Units: Percent change				
least squares mean (standard error)	-0.50 ( $\pm$ 0.184)	-3.47 ( $\pm$ 0.183)	-4.12 ( $\pm$ 0.185)	

## Statistical analyses

<b>Statistical analysis title</b>	Statistical analysis
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2813
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-2.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.472
upper limit	-2.454
Variability estimate	Standard error of the mean
Dispersion value	0.26

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2786
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-3.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.125
upper limit	-3.103
Variability estimate	Standard error of the mean
Dispersion value	0.261

## Secondary: Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic

**Blood Pressure (DBP) at end-of-Treatment**

End point title	Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at end-of-Treatment
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End point description:

Change from baseline in SBP and DBP were assessed. On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and post-baseline blood pressure measurements.

End point type	Secondary
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End point timeframe:

Baseline and end of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1398	1415	1388	
Units: Millimeter of mercury (mmHg)				
least squares mean (standard error)				
SBP(Change from baseline at end of treatment)	-1.96 (± 0.377)	-4.91 (± 0.375)	-6.49 (± 0.378)	
DBP (Change from baseline at end of treatment)	-2.88 (± 0.223)	-3.70 (± 0.221)	-4.51 (± 0.223)	

**Statistical analyses**

<b>Statistical analysis title</b>	Statistical analysis 1 (Systolic blood pressure)
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2813
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-2.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.998
upper limit	-1.914
Variability estimate	Standard error of the mean
Dispersion value	0.532

<b>Statistical analysis title</b>	Statistical analysis 2 (Systolic blood pressure)
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 300 mg
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Number of subjects included in analysis	2786
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-4.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.579
upper limit	-3.484
Variability estimate	Standard error of the mean
Dispersion value	0.534

<b>Statistical analysis title</b>	Statistical analysis 3 (Diastolic blood pressure)
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2786
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-0.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.437
upper limit	-0.205
Variability estimate	Standard error of the mean
Dispersion value	0.314

<b>Statistical analysis title</b>	Statistical analysis 4 (Diastolic blood pressure)
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2786
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	-1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.245
upper limit	-1.007
Variability estimate	Standard error of the mean
Dispersion value	0.316

## Secondary: Change From Baseline in Triglycerides Levels at end-of-Treatment

End point title	Change From Baseline in Triglycerides Levels at end-of-Treatment
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End point description:

Change from baseline in triglycerides levels was assessed. On treatment set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint.

End point type	Secondary
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End point timeframe:

Baseline and end of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1325	1371	1321	
Units: mmol/L				
arithmetic mean (standard deviation)	0.05 ( $\pm$ 1.597)	0.13 ( $\pm$ 1.679)	0.09 ( $\pm$ 1.238)	

## Statistical analyses

Statistical analysis title	Statistical analysis 1 (Triglycerides)
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2696
Analysis specification	Pre-specified
Analysis type	other
Method	Wilcoxon rank sum test
Parameter estimate	Hodges-Lehman Estimate
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.07

Statistical analysis title	Statistical analysis 2 (Triglycerides)
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Statistical analysis description:

Comparison for canagliflozin versus placebo is reported here.

Comparison groups	Placebo v Canagliflozin 300 mg
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Number of subjects included in analysis	2646
Analysis specification	Pre-specified
Analysis type	other
Method	Wilcoxon rank sum test
Parameter estimate	Hodges-Lehman Estimate
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.03
upper limit	0.08

## Secondary: Change from Baseline in Cholesterol, HDL-C and LDL-C Levels at end-of-Treatment

End point title	Change from Baseline in Cholesterol, HDL-C and LDL-C Levels at end-of-Treatment
End point description:	
Change from baseline in cholesterol, HDL-C and LDL-C Levels were assessed. On treatment set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and post-baseline lipid measurements.	
End point type	Secondary
End point timeframe:	
Baseline and end of treatment (approximately maximum 338 weeks)	

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1325	1371	1321	
Units: mmol/L				
least squares mean (standard error)				
Cholesterol (change from baseline at EOT)	-0.07 (± 0.028)	0.11 (± 0.027)	0.16 (± 0.028)	
HDL-C (change from baseline at EOT)	-0.01 (± 0.006)	0.04 (± 0.006)	0.05 (± 0.006)	
LDL-C (change from baseline at EOT)	-0.07 (± 0.022)	0.04 (± 0.022)	0.10 (± 0.023)	

## Statistical analyses

Statistical analysis title	Statistical analysis 1 (Cholesterol)
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg



Number of subjects included in analysis	2696
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.105
upper limit	0.259
Variability estimate	Standard error of the mean
Dispersion value	0.039

<b>Statistical analysis title</b>	Statistical analysis 2 (Cholesterol)
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2646
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.152
upper limit	0.307
Variability estimate	Standard error of the mean
Dispersion value	0.039

<b>Statistical analysis title</b>	Statistical analysis 3 (HDL-C)
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2696
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.031
upper limit	0.065
Variability estimate	Standard error of the mean
Dispersion value	0.009

<b>Statistical analysis title</b>	Statistical analysis 4 (HDL-C)
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2646
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	0.075
Variability estimate	Standard error of the mean
Dispersion value	0.009

<b>Statistical analysis title</b>	Statistical analysis 5 (LDL-C)
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg
Number of subjects included in analysis	2696
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.046
upper limit	0.17
Variability estimate	Standard error of the mean
Dispersion value	0.032

<b>Statistical analysis title</b>	Statistical analysis 6 (LDL-C)
Statistical analysis description: Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg

Number of subjects included in analysis	2646
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.102
upper limit	0.226
Variability estimate	Standard error of the mean
Dispersion value	0.032

### Secondary: Change from Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) to High-Density Lipoprotein-Cholesterol (HDL-C) Ratio at end-of-Treatment

End point title	Change from Baseline in Low-Density Lipoprotein-Cholesterol (LDL-C) to High-Density Lipoprotein-Cholesterol (HDL-C) Ratio at end-of-Treatment
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End point description:

Change from baseline in LDL-C to HDL-C ratio was assessed. On treatment set included all randomized subjects who were treated and received at least 1 dose of study drug. Here 'N' signifies number of subjects who were evaluable for this endpoint who had both baseline and post-baseline lipid measurements.

End point type	Secondary
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End point timeframe:

Baseline and end of treatment (approximately maximum 338 weeks)

End point values	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1325	1371	1321	
Units: Ratio				
least squares mean (standard error)	-0.04 (± 0.021)	-0.02 (± 0.021)	0.00 (± 0.021)	

### Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 100 mg

Number of subjects included in analysis	2696
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.076
Variability estimate	Standard error of the mean
Dispersion value	0.03

<b>Statistical analysis title</b>	Statistical analysis 2
Statistical analysis description:	
Comparison for canagliflozin versus placebo is reported here.	
Comparison groups	Placebo v Canagliflozin 300 mg
Number of subjects included in analysis	2646
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference of Least Square Mean
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.023
upper limit	0.094
Variability estimate	Standard error of the mean
Dispersion value	0.03

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Approximately 8 years

Adverse event reporting additional description:

On-treatment analysis set included all randomized subjects who were treated and received at least 1 dose of study drug. The number of deaths (all causes) is adjudicated death that occurred within 30 days of the last dose of the study drug.

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.1
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### Reporting groups

Reporting group title	Placebo
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Reporting group description:

Subjects received one placebo capsule orally once daily for the duration of the study or until early discontinuation from treatment.

Reporting group title	Canagliflozin 100 mg
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Reporting group description:

Subjects received one canagliflozin 100 mg capsule once daily for the duration of the study or until early discontinuation from treatment.

Reporting group title	Canagliflozin 300 mg
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Reporting group description:

Subjects received one canagliflozin 300 mg capsule once daily for the duration of the study or until early discontinuation from treatment.

Serious adverse events	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	584 / 1441 (40.53%)	601 / 1445 (41.59%)	606 / 1441 (42.05%)
number of deaths (all causes)	74	68	66
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute Leukaemia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Adenocarcinoma Gastric			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Adenocarcinoma of Colon			
subjects affected / exposed	2 / 1441 (0.14%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenolymphoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenosquamous Cell Lung Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal Adenoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Anal Squamous Cell Carcinoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendix Adenoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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	2 / 1441 (0.14%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Bladder			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Prostate			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Peritoneal Neoplasm			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Bile Duct Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Bladder Cancer			
subjects affected / exposed	5 / 1441 (0.35%)	4 / 1445 (0.28%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	2 / 5	1 / 4	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 1	0 / 0
Bladder Cancer Stage 0, with Cancer in Situ			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Papilloma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Transitional Cell Carcinoma			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	1 / 3	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 8
deaths causally related to treatment / all	1 / 2	0 / 0	0 / 1
Breast Cancer Recurrent			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 I			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Bronchial Carcinoma			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Bronchial Neoplasm Benign			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid Tumour Pulmonary			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid Tumour of the Duodenum			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Body Tumour			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Cholangiocarcinoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrosarcoma			



subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondrosarcoma Metastatic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Chronic Myeloid Leukaemia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Myelomonocytic Leukaemia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Clear Cell Renal Cell Carcinoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Adenoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
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			
subjects affected / exposed	4 / 1441 (0.28%)	1 / 1445 (0.07%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Colon Cancer Metastatic			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Colon Cancer Stage Iii			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diffuse Large B-Cell Lymphoma			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Endometrial Adenocarcinoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Endometrial Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gallbladder Cancer Metastatic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Cancer			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Tract Adenoma			

subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head and Neck Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Hepatic Cancer Metastatic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Hepatocellular Carcinoma			
subjects affected / exposed	3 / 1441 (0.21%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's Disease			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Kidney Angiomyolipoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Cell Lung Cancer			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Large Intestine Benign Neoplasm			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Laryngeal Squamous Cell Carcinoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lentigo Maligna			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Adenocarcinoma			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Lung Adenocarcinoma Metastatic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Cancer Metastatic			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 1
Lung Neoplasm Malignant			

subjects affected / exposed	4 / 1441 (0.28%)	3 / 1445 (0.21%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 3
Lung Squamous Cell Carcinoma Stage 0			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic Lymphoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Malignant Melanoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melanocytic Naevus			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Bone			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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 Central Nervous System			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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 Lymph Nodes			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to Peritoneum			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Metastases to Small Intestine			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Carcinoid Tumour			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic Carcinoma of the Bladder			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Metastatic Malignant Melanoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic Renal Cell Carcinoma			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Monoclonal Gammopathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Myelodysplastic Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myeloid Leukaemia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myeloproliferative Neoplasm			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine Carcinoma Metastatic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Neuroendocrine Carcinoma of the Skin			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Small Cell Lung Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Non-Small Cell Lung Cancer Stage Iv			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Oesophageal Adenocarcinoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ovarian Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Ovarian Cancer Metastatic			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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	3 / 1441 (0.21%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Pancreatic Carcinoma Metastatic			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Pancreatic Neoplasm			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Papillary Serous Endometrial Carcinoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary Thyroid Cancer			



subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic Syndrome			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Parathyroid Tumour Benign			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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			
subjects affected / exposed	7 / 1441 (0.49%)	8 / 1445 (0.55%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 7	1 / 9	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer Metastatic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Prostatic Adenoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Adenocarcinoma			

subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Rectal Adenoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer Recurrent			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Rectosigmoid Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
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			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Cancer Metastatic			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal Cancer Stage I			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Cell Carcinoma			

subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Renal Cell Carcinoma Stage Ii			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Neoplasm			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Oncocytoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sarcoma Uterus			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Seminoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Squamous Cell Carcinoma of Skin			

subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Squamous Cell Carcinoma of the Oral Cavity			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous Cell Carcinoma of the Tongue			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Superficial Spreading Melanoma Stage Unspecified			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular Seminoma (Pure)			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Adenoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Cancer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Tonsil Cancer			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional Cell Cancer of the Renal Pelvis and Ureter			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Transitional Cell Carcinoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Cancer			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal Warts			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 disorders			
Accelerated Hypertension			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Aneurysm			
subjects affected / exposed	4 / 1441 (0.28%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Stenosis			

subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Arterial Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Arterial Thrombosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Pressure Inadequately Controlled			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory Collapse			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Deep Vein Thrombosis			
subjects affected / exposed	3 / 1441 (0.21%)	4 / 1445 (0.28%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Dry Gangrene			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity Necrosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	0 / 1441 (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
Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	10 / 1441 (0.69%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 14	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	4 / 1441 (0.28%)	5 / 1445 (0.35%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Emergency			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	3 / 1441 (0.21%)	5 / 1445 (0.35%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	1 / 3	1 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac Artery Occlusion			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Intermittent Claudication			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Lymphoedema			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Hypertension			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurogenic Shock			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Orthostatic Hypotension			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Arterial Occlusive Disease			



subjects affected / exposed	4 / 1441 (0.28%)	12 / 1445 (0.83%)	11 / 1441 (0.76%)
occurrences causally related to treatment / all	0 / 4	2 / 19	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Aneurysm			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Occlusion			
subjects affected / exposed	1 / 1441 (0.07%)	7 / 1445 (0.48%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Stenosis			
subjects affected / exposed	4 / 1441 (0.28%)	5 / 1445 (0.35%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	0 / 9	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Thrombosis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
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 Ischaemia			
subjects affected / exposed	9 / 1441 (0.62%)	9 / 1445 (0.62%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 11	0 / 10	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	7 / 1441 (0.49%)	8 / 1445 (0.55%)	10 / 1441 (0.69%)
occurrences causally related to treatment / all	0 / 9	0 / 8	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Subclavian Artery Stenosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis Superficial			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Varicose Vein			
subjects affected / exposed	3 / 1441 (0.21%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Arrhythmia Prophylaxis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture Treatment			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Bypass			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Arthroplasty			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional Hernia Repair			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Adverse Drug Reaction			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Application Site Dermatitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Chest Discomfort			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
subjects affected / exposed	23 / 1441 (1.60%)	26 / 1445 (1.80%)	13 / 1441 (0.90%)
occurrences causally related to treatment / all	0 / 26	0 / 28	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complication Associated with Device			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	8 / 1441 (0.56%)	8 / 1445 (0.55%)	8 / 1441 (0.56%)
occurrences causally related to treatment / all	0 / 8	0 / 8	0 / 8
deaths causally related to treatment / all	0 / 8	0 / 8	0 / 8
Drug Intolerance			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Facial Pain			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Fatigue</b>			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
<b>Generalised Oedema</b>			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
<b>Impaired Healing</b>			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
<b>Ischaemic Ulcer</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Medical Device Site Reaction</b>			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Multiple Organ Dysfunction Syndrome</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
<b>Necrosis</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Non-Cardiac Chest Pain</b>			

subjects affected / exposed	2 / 1441 (0.14%)	8 / 1445 (0.55%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema Peripheral			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perforated Ulcer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Swelling			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 3	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strangulated Hernia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Cardiac Death			
subjects affected / exposed	5 / 1441 (0.35%)	0 / 1445 (0.00%)	9 / 1441 (0.62%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 5	0 / 0	0 / 9
Sudden Death			
subjects affected / exposed	6 / 1441 (0.42%)	5 / 1445 (0.35%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 6	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 6	0 / 5	0 / 3
Vascular Stent Occlusion			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Stent Restenosis			
subjects affected / exposed	2 / 1441 (0.14%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Atopy			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Hypersensitivity			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Food Allergy			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Acquired Phimosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenomyosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Prostatic Hyperplasia			
subjects affected / exposed	1 / 1441 (0.07%)	8 / 1445 (0.55%)	15 / 1441 (1.04%)
occurrences causally related to treatment / all	0 / 1	0 / 8	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cervical Dysplasia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystocele			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Hyperplasia			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Epididymal Cyst			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erectile Dysfunction			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Prolapse			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis Noninfective			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Prolapse			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic Calcification			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatomegaly			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectocele			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Polyp			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Prolapse			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterovaginal Prolapse			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	0 / 1441 (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
Vaginal Prolapse			



subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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, thoracic and mediastinal disorders			
Acute Pulmonary Oedema			
subjects affected / exposed	6 / 1441 (0.42%)	3 / 1445 (0.21%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Respiratory Distress Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	3 / 1445 (0.21%)	0 / 1441 (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
Acute Respiratory Failure			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Asthma			
subjects affected / exposed	3 / 1441 (0.21%)	4 / 1445 (0.28%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial Hyperreactivity			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	7 / 1441 (0.49%)	7 / 1445 (0.48%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	0 / 10	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Diaphragmatic Disorder			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Dyspnoea			
subjects affected / exposed	8 / 1441 (0.56%)	11 / 1445 (0.76%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	0 / 10	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dyspnoea Exertional			
subjects affected / exposed	3 / 1441 (0.21%)	4 / 1445 (0.28%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic Pulmonary Fibrosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Interstitial Lung Disease			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal Oedema			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Consolidation			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Infiltration			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal Polyps			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Organising Pneumonia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural Effusion			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Pneumonitis			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Pneumothorax			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive Cough			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	7 / 1441 (0.49%)	5 / 1445 (0.35%)	9 / 1441 (0.62%)
occurrences causally related to treatment / all	0 / 7	0 / 5	1 / 9
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 1
Pulmonary Fibrosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Pulmonary Hypertension			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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	3 / 1441 (0.21%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary Vein Stenosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Acidosis			

subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Respiratory Arrest			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory Distress			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory Failure			
subjects affected / exposed	6 / 1441 (0.42%)	3 / 1445 (0.21%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 9	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 1
Sinus Polyp			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Apnoea Syndrome			
subjects affected / exposed	4 / 1441 (0.28%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Affective Disorder			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Anxiety			

subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Completed Suicide			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Confusional State			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Tremens			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Hallucination, Visual			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Insomnia			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major Depression			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Mental Status Changes			
subjects affected / exposed	4 / 1441 (0.28%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Paranoia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schizophrenia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Cognitive Impairment			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device Breakage			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Damage			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Hepatobiliary disorders			
Alcoholic Liver Disease			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile Duct Obstruction			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Bile Duct Stone			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Cholangitis Acute			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Cholecystitis			



subjects affected / exposed	2 / 1441 (0.14%)	5 / 1445 (0.35%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Acute			
subjects affected / exposed	4 / 1441 (0.28%)	6 / 1445 (0.42%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cholecystitis Chronic			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	11 / 1441 (0.76%)	9 / 1445 (0.62%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	0 / 11	0 / 11	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-Induced Liver Injury			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Gallbladder Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Gallbladder Pain			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Gallbladder Perforation			

subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Gallbladder Polyp			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Cirrhosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic Failure			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic Fibrosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Steatosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatomegaly			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Hepatorenal Syndrome			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Jaundice Cholestatic			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Alcoholic Steatohepatitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Portal Hypertension			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal Vein Thrombosis			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Cholecystectomy Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Creatinine Increased			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Blood Glucose Abnormal			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Glucose Increased			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Pressure Abnormal			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Pressure Decreased			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Pressure Increased			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Stress Test Abnormal			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Catheterisation Cardiac			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Test Positive			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Colonoscopy			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram Abnormal			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocardiogram St Segment Depression			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 St-T Segment Abnormal			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exercise Test Abnormal			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-Glutamyltransferase Increased			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerular Filtration Rate Decreased			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular Pressure Increased			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Function Test Increased			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precancerous Cells Present			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Function Test Abnormal			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight Decreased			
subjects affected / exposed	3 / 1441 (0.21%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Overdose			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum Fracture			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Alcohol Poisoning			
subjects affected / exposed	3 / 1441 (0.21%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaesthetic Complication			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	6 / 1445 (0.42%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Bypass Occlusion			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Arterial Bypass Stenosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Contusion			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain Contusion			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Concussion			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Restenosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral Injury			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dural Tear			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Bones Fracture			



subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Fall			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	4 / 1445 (0.28%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 4	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign Body			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign Body in Eye			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture Displacement			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Injury			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Heat Stroke			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			
subjects affected / exposed	3 / 1441 (0.21%)	4 / 1445 (0.28%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	0 / 3	0 / 4	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	2 / 1441 (0.14%)	4 / 1445 (0.28%)	8 / 1441 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 4	1 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Injury			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Laceration			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Ligament Sprain			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Rupture			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Overdose			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Patella Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Fracture			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Artery Restenosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Concussion Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Bile Leak			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Complication			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Renal Failure			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Postoperative Respiratory Failure			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Thoracic Procedure Complication			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Wound Complication			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Procedural Nausea			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Vomiting			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pubis Fracture			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	8 / 1441 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Skin Injury			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fractured Base			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Compression Fracture			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Injury			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sternal Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Stomal Hernia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Subarachnoid Haemorrhage			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Haematoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Subdural Haematoma			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Injury			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
<b>Tendon Rupture</b>			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	0 / 1441 (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
<b>Thermal Burn</b>			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Thoracic Vertebral Fracture</b>			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
<b>Tibia Fracture</b>			
subjects affected / exposed	0 / 1441 (0.00%)	4 / 1445 (0.28%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	2 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Traumatic Haematoma</b>			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
<b>Traumatic Intracranial Haemorrhage</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
<b>Ulna Fracture</b>			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
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>Upper Limb Fracture</b>			



subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention Postoperative			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular Graft Complication			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Pseudoaneurysm			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Complication			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Necrosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Congenital, familial and genetic disorders			
Arteriovenous Malformation			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental Hip Dysplasia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Hydrocele			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitello-Intestinal Duct Remnant			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Coronary Syndrome			
subjects affected / exposed	8 / 1441 (0.56%)	3 / 1445 (0.21%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Acute Left Ventricular Failure			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Myocardial Infarction			
subjects affected / exposed	10 / 1441 (0.69%)	10 / 1445 (0.69%)	8 / 1441 (0.56%)
occurrences causally related to treatment / all	0 / 10	1 / 10	0 / 9
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 2
Adams-Stokes Syndrome			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	24 / 1441 (1.67%)	15 / 1445 (1.04%)	30 / 1441 (2.08%)
occurrences causally related to treatment / all	0 / 30	0 / 16	0 / 38
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Angina Unstable			
subjects affected / exposed	20 / 1441 (1.39%)	24 / 1445 (1.66%)	28 / 1441 (1.94%)
occurrences causally related to treatment / all	1 / 24	1 / 28	0 / 34
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anginal Equivalent			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Incompetence			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic Valve Stenosis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	3 / 1441 (0.21%)	0 / 1445 (0.00%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Arteriosclerosis Coronary Artery			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Atrial Fibrillation			

subjects affected / exposed	26 / 1441 (1.80%)	22 / 1445 (1.52%)	17 / 1441 (1.18%)
occurrences causally related to treatment / all	0 / 27	0 / 28	1 / 28
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrial Flutter			
subjects affected / exposed	6 / 1441 (0.42%)	6 / 1445 (0.42%)	8 / 1441 (0.56%)
occurrences causally related to treatment / all	0 / 7	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block Complete			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular Block Second Degree			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	4 / 1441 (0.28%)	2 / 1445 (0.14%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	1 / 4	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
subjects affected / exposed	6 / 1441 (0.42%)	7 / 1445 (0.48%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 6	1 / 7	0 / 6
deaths causally related to treatment / all	0 / 5	0 / 4	0 / 5
Cardiac Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure			

subjects affected / exposed	19 / 1441 (1.32%)	19 / 1445 (1.31%)	23 / 1441 (1.60%)
occurrences causally related to treatment / all	1 / 23	0 / 28	1 / 28
deaths causally related to treatment / all	0 / 1	0 / 5	0 / 3
Cardiac Failure Acute			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Cardiac Failure Chronic			
subjects affected / exposed	5 / 1441 (0.35%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac Failure Congestive			
subjects affected / exposed	20 / 1441 (1.39%)	15 / 1445 (1.04%)	14 / 1441 (0.97%)
occurrences causally related to treatment / all	0 / 28	0 / 23	0 / 15
deaths causally related to treatment / all	0 / 4	0 / 2	0 / 3
Cardio-Respiratory Arrest			
subjects affected / exposed	2 / 1441 (0.14%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 2	1 / 3	0 / 0
Cardiogenic Shock			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 3
Cardiomyopathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular Disorder			

subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cor Pulmonale			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	24 / 1441 (1.67%)	24 / 1445 (1.66%)	23 / 1441 (1.60%)
occurrences causally related to treatment / all	0 / 25	0 / 28	0 / 24
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Coronary Artery Insufficiency			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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	2 / 1441 (0.14%)	2 / 1445 (0.14%)	0 / 1441 (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
Coronary Artery Stenosis			
subjects affected / exposed	5 / 1441 (0.35%)	5 / 1445 (0.35%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Thrombosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Hypertensive Heart Disease			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Left Ventricular Dysfunction			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
Left Ventricular Failure			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Incompetence			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Fibrosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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	16 / 1441 (1.11%)	18 / 1445 (1.25%)	11 / 1441 (0.76%)
occurrences causally related to treatment / all	0 / 17	0 / 18	0 / 11
deaths causally related to treatment / all	0 / 4	0 / 11	0 / 7
Myocardial Ischaemia			
subjects affected / exposed	9 / 1441 (0.62%)	11 / 1445 (0.76%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 11	1 / 14	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Palpitations			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Pericardial Effusion			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis Constrictive			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless Electrical Activity			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Restrictive Cardiomyopathy			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right Ventricular Failure			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Sinus Bradycardia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Node Dysfunction			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular Tachycardia			
subjects affected / exposed	6 / 1441 (0.42%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			



subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Arrhythmia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Extrasystoles			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Fibrillation			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Ventricular Tachycardia			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Alcoholic Seizure			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic Lateral Sclerosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal Ganglia Infarction			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basilar Artery Occlusion			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brain Injury			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain Stem Haemorrhage			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Brain Stem Infarction			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Carotid Arteriosclerosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	5 / 1441 (0.35%)	5 / 1445 (0.35%)	11 / 1441 (0.76%)
occurrences causally related to treatment / all	0 / 6	0 / 7	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Sinus Syndrome			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar Ataxia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar Infarction			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Arteriosclerosis			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
Cerebral Haemorrhage			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebral Infarction			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	1 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular Accident			
subjects affected / exposed	10 / 1441 (0.69%)	13 / 1445 (0.90%)	13 / 1441 (0.90%)
occurrences causally related to treatment / all	1 / 10	0 / 13	0 / 13
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 6
Cervicobrachial Syndrome			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
<b>Coma</b>			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
<b>Cubital Tunnel Syndrome</b>			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Depressed Level of Consciousness</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diabetic Coma</b>			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diabetic Hyperosmolar Coma</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Diabetic Neuropathy</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Dizziness</b>			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
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>Encephalopathy</b>			

subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paralysis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Paresis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised Tonic-Clonic Seizure			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Haemorrhage Intracranial			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhagic Stroke			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Headache			

subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	0 / 1441 (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
Hemiparesis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Encephalopathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic Coma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemic Encephalopathy			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal Neuralgia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial Haematoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic Stroke			
subjects affected / exposed	4 / 1441 (0.28%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	1 / 4	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 2	0 / 2	0 / 0
Lacunar Infarction			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar Stroke			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Radiculopathy			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbosacral Radiculopathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Impairment			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Motor Dysfunction			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenia Gravis			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Intolerance			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Paralysis Recurrent Laryngeal Nerve			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Parkinson's Disease			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial Seizures			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Petit Mal Epilepsy			



subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Herpetic Neuralgia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiculopathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reversible Cerebral Vasoconstriction Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
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	2 / 1441 (0.14%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serotonin Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Somnolence			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Claudication			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Compression			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	7 / 1441 (0.49%)	9 / 1445 (0.62%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 7	0 / 9	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	15 / 1441 (1.04%)	7 / 1445 (0.48%)	16 / 1441 (1.11%)
occurrences causally related to treatment / all	0 / 16	0 / 8	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Encephalopathy			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebrobasilar Insufficiency			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vertigo CNS Origin			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vith Nerve Paralysis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal Cord Paralysis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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	8 / 1441 (0.56%)	2 / 1445 (0.14%)	7 / 1441 (0.49%)
occurrences causally related to treatment / all	1 / 8	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic Anaemia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypochromic Anaemia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic Anaemia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Normochromic Normocytic Anaemia			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Pancytopenia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pernicious Anaemia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness Neurosensory			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoacusis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Vertigo			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo Positional			

subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis Fugax			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness Unilateral			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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			
subjects affected / exposed	8 / 1441 (0.56%)	8 / 1445 (0.55%)	10 / 1441 (0.69%)
occurrences causally related to treatment / all	0 / 9	0 / 10	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract Diabetic			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract Nuclear			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Cataract Subcapsular			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
Dacryostenosis Acquired			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Retinopathy			

subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplopia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exophthalmos			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye Haemorrhage			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid Ptosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Glaucoma			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lens Dislocation			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular Degeneration			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular Fibrosis			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macular Hole			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Maculopathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Ocular Myasthenia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open Angle Glaucoma			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic Ischaemic Neuropathy			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
Retinal Vascular Thrombosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinopathy Proliferative			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcerative Keratitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual Impairment			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Vitreous Floaters			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Hernia			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Incarcerated Hernia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain			
subjects affected / exposed	4 / 1441 (0.28%)	3 / 1445 (0.21%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Upper			



subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Abdominal Wall Haematoma			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal Fissure			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Anal Fistula			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 / 1441 (0.07%)	1 / 1445 (0.07%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowel Movement Irregularity			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Gastritis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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 Ischaemic			

subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	0 / 1441 (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
Colitis Microscopic			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Ulcerative			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Colon Dysplasia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Colonic Pseudo-Obstruction			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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	2 / 1441 (0.14%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dieulafoy's Vascular Malformation			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum Intestinal			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum Intestinal Haemorrhagic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal Ulcer			
subjects affected / exposed	4 / 1441 (0.28%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	1 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Dysphagia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erosive Duodenitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Eructation			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Food Poisoning			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallstone Ileus			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Mucosal Hypertrophy			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Perforation			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Gastric Ulcer			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer Perforation			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Gastritis			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Erosion			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			

subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Necrosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Obstruction			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Haemorrhoids			
subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	0 / 1441 (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
Hernial Eventration			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Ileus			
subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	0 / 1441 (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
Ileus Paralytic			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated Umbilical Hernia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 1441 (0.00%)	3 / 1445 (0.21%)	0 / 1441 (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
Intestinal Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Intestinal Ischaemia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Intestinal Polyp			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Intra-Abdominal Haemorrhage			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Perforation			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Lower Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Achalasia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Oesophageal Obstruction			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Oesophageal Ulcer			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal Varices Haemorrhage			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Cyst			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Pseudocyst			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	1 / 1441 (0.07%)	4 / 1445 (0.28%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Haemorrhagic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Pancreatitis Necrotising			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic Ulcer			



subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Haemorrhage			
subjects affected / exposed	4 / 1441 (0.28%)	6 / 1445 (0.42%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	1 / 4	0 / 7	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Ulcer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 / 1441 (0.00%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	3 / 1441 (0.21%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Varices Oesophageal			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Decubitus Ulcer			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Dermatitis Contact			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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			
subjects affected / exposed	4 / 1441 (0.28%)	9 / 1445 (0.62%)	10 / 1441 (0.69%)
occurrences causally related to treatment / all	0 / 5	0 / 10	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Neuropathic Ulcer			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Ulcer			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Drug Eruption			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Eczema			

subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Guttate Psoriasis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperhidrosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity Vasculitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keloid Scar			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen Planus			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Necrobiosis Lipoidica Diabeticorum			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Neurodermatitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Lesion			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Ulcer			
subjects affected / exposed	2 / 1441 (0.14%)	10 / 1445 (0.69%)	14 / 1441 (0.97%)
occurrences causally related to treatment / all	0 / 2	0 / 11	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
subjects affected / exposed	13 / 1441 (0.90%)	15 / 1445 (1.04%)	8 / 1441 (0.56%)
occurrences causally related to treatment / all	1 / 14	0 / 16	2 / 8
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Azotaemia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Bladder Neck Obstruction			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Prolapse			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder Stenosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Bladder			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Calculus Urinary			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Kidney Disease			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis Haemorrhagic			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Nephropathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysuria			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Haematuria			

subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	7 / 1441 (0.49%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 7	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oliguria			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Renal Artery Stenosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Colic			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Failure			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Impairment			
subjects affected / exposed	1 / 1441 (0.07%)	6 / 1445 (0.42%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	1 / 1	5 / 7	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Papillary Necrosis			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Tubular Necrosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress Urinary Incontinence			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Terminal Dribbling			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Tubulointerstitial Nephritis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric Obstruction			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Ureterolithiasis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Meatus Stenosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral Stenosis			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Bladder Polyp			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Urinary Incontinence			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Urinary Retention			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Obstruction			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Empty Sella Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism Primary			



subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate Antidiuretic Hormone Secretion			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Thyroiditis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Acquired Claw Toe			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankylosing Spondylitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	3 / 1441 (0.21%)	5 / 1445 (0.35%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	2 / 1441 (0.14%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back Pain			

subjects affected / exposed	3 / 1441 (0.21%)	5 / 1445 (0.35%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Atrophy			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone Cyst			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondropathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Arthropathy			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dupuytren's Contracture			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank Pain			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gouty Arthritis			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
Gouty Tophus			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemarthrosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Compression			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Degeneration			

subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	0 / 1441 (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
Intervertebral Disc Disorder			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
Intervertebral Disc Protrusion			
subjects affected / exposed	4 / 1441 (0.28%)	3 / 1445 (0.21%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 5	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Juvenile Idiopathic Arthritis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 1441 (0.00%)	8 / 1445 (0.55%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus-Like Syndrome			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Atrophy			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Neck Pain			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathic Arthropathy			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	27 / 1441 (1.87%)	30 / 1445 (2.08%)	23 / 1441 (1.60%)
occurrences causally related to treatment / all	0 / 30	0 / 39	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			

subjects affected / exposed	4 / 1441 (0.28%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periarthritis			
subjects affected / exposed	0 / 1441 (0.00%)	3 / 1445 (0.21%)	0 / 1441 (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
Polyarthritis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polymyalgia Rheumatica			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic Arthropathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Rotator Cuff Syndrome			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Senile Osteoporosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Column Stenosis			
subjects affected / exposed	6 / 1441 (0.42%)	4 / 1445 (0.28%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 6	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			

subjects affected / exposed	4 / 1441 (0.28%)	3 / 1445 (0.21%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Spondyloarthropathy			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Spondylolisthesis			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	0 / 1441 (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
Synovial Cyst			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Disorder			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Tendonitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tenosynovitis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertebral Foraminal Stenosis			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Infections and infestations</b>			
<b>Abdominal Abscess</b>			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
<b>Abdominal Sepsis</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
<b>Abscess</b>			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess Limb</b>			
subjects affected / exposed	4 / 1441 (0.28%)	5 / 1445 (0.35%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anal Abscess</b>			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	0 / 1441 (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
<b>Appendicitis</b>			
subjects affected / exposed	2 / 1441 (0.14%)	3 / 1445 (0.21%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Appendicitis Perforated</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
<b>Arthritis Bacterial</b>			



subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Infective			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical Pneumonia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Bacterial Sepsis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary Sepsis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Bronchitis			
subjects affected / exposed	4 / 1441 (0.28%)	5 / 1445 (0.35%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 5	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis Bacterial			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary Aspergillosis			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burn Infection			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbuncle			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	19 / 1441 (1.32%)	15 / 1445 (1.04%)	15 / 1441 (1.04%)
occurrences causally related to treatment / all	1 / 19	0 / 25	0 / 16
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cellulitis Gangrenous			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis Staphylococcal			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Cholecystitis Infective			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Hepatitis B			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Chronic Sinusitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Colitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium Difficile Infection			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon Gangrene			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Dengue Fever			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Foot Infection			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Gangrene			

subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Bacteraemia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Epiglottitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	5 / 1441 (0.35%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia Urinary Tract Infection			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye Infection			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Eye Infection Fungal			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Gangrene			
subjects affected / exposed	4 / 1441 (0.28%)	15 / 1445 (1.04%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 4	0 / 17	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	6 / 1441 (0.42%)	5 / 1445 (0.35%)	8 / 1441 (0.56%)
occurrences causally related to treatment / all	0 / 7	0 / 6	1 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Infection			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin Abscess			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin Infection			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma Infection			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Helicobacter Infection			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Herpes Zoster			
subjects affected / exposed	1 / 1441 (0.07%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiv Infection			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Cyst			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Dermal Cyst			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Infected Skin Ulcer			
subjects affected / exposed	2 / 1441 (0.14%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective Exacerbation of Bronchiectasis			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Influenza			
subjects affected / exposed	0 / 1441 (0.00%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intervertebral Discitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella Infection			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Leptospirosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Localised Infection			
subjects affected / exposed	1 / 1441 (0.07%)	4 / 1445 (0.28%)	10 / 1441 (0.69%)
occurrences causally related to treatment / all	0 / 1	0 / 5	1 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection			

subjects affected / exposed	7 / 1441 (0.49%)	1 / 1445 (0.07%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Lymphangitis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Medical Device Site Infection			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Meningitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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 Viral			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising Fasciitis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nosocomial Infection			



subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Oesophageal Candidiasis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Oral Candidiasis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Osteomyelitis			
subjects affected / exposed	7 / 1441 (0.49%)	11 / 1445 (0.76%)	12 / 1441 (0.83%)
occurrences causally related to treatment / all	1 / 11	0 / 15	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis Chronic			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Externa			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis Media			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathogen Resistance			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Penile Infection			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Perineal Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perinephric Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Peritonsillar Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasmodium Vivax Infection			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	36 / 1441 (2.50%)	31 / 1445 (2.15%)	26 / 1441 (1.80%)
occurrences causally related to treatment / all	1 / 41	0 / 35	0 / 27
deaths causally related to treatment / all	0 / 2	0 / 6	0 / 2
Pneumonia Bacterial			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Influenzal			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Cellulitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
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	1 / 1441 (0.07%)	2 / 1445 (0.14%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Wound Infection			

subjects affected / exposed	5 / 1441 (0.35%)	2 / 1445 (0.14%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal Bacteraemia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Psoas Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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 Sepsis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Pulmonary Tuberculosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Pyelonephritis			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	1 / 3	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Acute			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis Chronic			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Pyoderma			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Tuberculosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Respiratory Tract Infection			
subjects affected / exposed	3 / 1441 (0.21%)	2 / 1445 (0.14%)	0 / 1441 (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
Respiratory Tract Infection Viral			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	0 / 1441 (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
Sepsis			
subjects affected / exposed	10 / 1441 (0.69%)	12 / 1445 (0.83%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 10	0 / 12	0 / 5
deaths causally related to treatment / all	0 / 4	0 / 3	0 / 3
Septic Shock			
subjects affected / exposed	3 / 1441 (0.21%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Sialoadenitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Sinusitis			
subjects affected / exposed	1 / 1441 (0.07%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft Tissue Infection			

subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Osteomyelitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 1441 (0.00%)	2 / 1445 (0.14%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Streptococcal Bacteraemia			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	0 / 1441 (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
Streptococcal Infection			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Streptococcal Sepsis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection Bacterial			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth Infection			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (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
Tracheobronchitis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid Fever			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	16 / 1441 (1.11%)	15 / 1445 (1.04%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	9 / 16	9 / 15	3 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	4 / 1441 (0.28%)	7 / 1445 (0.48%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	3 / 4	1 / 8	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vestibular Neuritis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Viral Infection			
subjects affected / exposed	1 / 1441 (0.07%)	3 / 1445 (0.21%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Pharyngitis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Vulval Abscess			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
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 Abscess			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
subjects affected / exposed	2 / 1441 (0.14%)	0 / 1445 (0.00%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Acidosis			



subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased Appetite			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	4 / 1441 (0.28%)	1 / 1445 (0.07%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	10 / 1441 (0.69%)	6 / 1445 (0.42%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	0 / 13	1 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus Inadequate Control			
subjects affected / exposed	7 / 1441 (0.49%)	3 / 1445 (0.21%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 8	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic Ketoacidosis			
subjects affected / exposed	1 / 1441 (0.07%)	4 / 1445 (0.28%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	0 / 1	3 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid Overload			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gout			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	4 / 1441 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	6 / 1441 (0.42%)	1 / 1445 (0.07%)	6 / 1441 (0.42%)
occurrences causally related to treatment / all	2 / 6	0 / 1	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	2 / 1441 (0.14%)	3 / 1445 (0.21%)	3 / 1441 (0.21%)
occurrences causally related to treatment / all	1 / 2	0 / 3	2 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hyperosmolar Hyperglycaemic State			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	8 / 1441 (0.56%)	12 / 1445 (0.83%)	12 / 1441 (0.83%)
occurrences causally related to treatment / all	4 / 10	3 / 12	4 / 12
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Hypokalaemia			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Hyponatraemia			
subjects affected / exposed	3 / 1441 (0.21%)	3 / 1445 (0.21%)	0 / 1441 (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
Hypoproteinaemia			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Ketoacidosis			
subjects affected / exposed	0 / 1441 (0.00%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ketosis			
subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	0 / 1441 (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
Lactic Acidosis			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	1 / 1441 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolic Acidosis			
subjects affected / exposed	2 / 1441 (0.14%)	1 / 1445 (0.07%)	2 / 1441 (0.14%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metabolic Disorder			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Syndrome			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	3 / 1441 (0.21%)	5 / 1445 (0.35%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 Diabetes Mellitus			

subjects affected / exposed	0 / 1441 (0.00%)	1 / 1445 (0.07%)	1 / 1441 (0.07%)
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>Vitamin B12 Deficiency</b>			
subjects affected / exposed	1 / 1441 (0.07%)	0 / 1445 (0.00%)	0 / 1441 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

<b>Non-serious adverse events</b>	Placebo	Canagliflozin 100 mg	Canagliflozin 300 mg
<b>Total subjects affected by non-serious adverse events</b>			
subjects affected / exposed	1137 / 1441 (78.90%)	1146 / 1445 (79.31%)	1167 / 1441 (80.99%)
<b>Vascular disorders</b>			
Hypertension			
subjects affected / exposed	123 / 1441 (8.54%)	77 / 1445 (5.33%)	75 / 1441 (5.20%)
occurrences (all)	163	103	91
Hypotension			
subjects affected / exposed	15 / 1441 (1.04%)	39 / 1445 (2.70%)	54 / 1441 (3.75%)
occurrences (all)	17	43	57
<b>General disorders and administration site conditions</b>			
Asthenia			
subjects affected / exposed	24 / 1441 (1.67%)	30 / 1445 (2.08%)	38 / 1441 (2.64%)
occurrences (all)	26	33	41
Chest Pain			
subjects affected / exposed	57 / 1441 (3.96%)	63 / 1445 (4.36%)	61 / 1441 (4.23%)
occurrences (all)	70	77	72
Fatigue			
subjects affected / exposed	57 / 1441 (3.96%)	59 / 1445 (4.08%)	59 / 1441 (4.09%)
occurrences (all)	69	72	67
Oedema Peripheral			
subjects affected / exposed	86 / 1441 (5.97%)	54 / 1445 (3.74%)	62 / 1441 (4.30%)
occurrences (all)	103	60	71
Pyrexia			

subjects affected / exposed occurrences (all)	47 / 1441 (3.26%) 60	39 / 1445 (2.70%) 44	35 / 1441 (2.43%) 45
Thirst subjects affected / exposed occurrences (all)	1 / 1441 (0.07%) 1	19 / 1445 (1.31%) 20	29 / 1441 (2.01%) 32
Reproductive system and breast disorders			
Balanoposthitis subjects affected / exposed occurrences (all)	25 / 1441 (1.73%) 29	87 / 1445 (6.02%) 144	100 / 1441 (6.94%) 181
Benign Prostatic Hyperplasia subjects affected / exposed occurrences (all)	29 / 1441 (2.01%) 29	37 / 1445 (2.56%) 38	36 / 1441 (2.50%) 37
Vulvovaginal Pruritus subjects affected / exposed occurrences (all)	7 / 1441 (0.49%) 7	29 / 1445 (2.01%) 43	21 / 1441 (1.46%) 35
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	104 / 1441 (7.22%) 145	103 / 1445 (7.13%) 120	97 / 1441 (6.73%) 115
Dyspnoea subjects affected / exposed occurrences (all)	47 / 1441 (3.26%) 55	39 / 1445 (2.70%) 44	42 / 1441 (2.91%) 58
Oropharyngeal Pain subjects affected / exposed occurrences (all)	33 / 1441 (2.29%) 40	41 / 1445 (2.84%) 49	34 / 1441 (2.36%) 40
Psychiatric disorders			
Depression subjects affected / exposed occurrences (all)	33 / 1441 (2.29%) 34	39 / 1445 (2.70%) 42	38 / 1441 (2.64%) 43
Insomnia subjects affected / exposed occurrences (all)	37 / 1441 (2.57%) 37	29 / 1445 (2.01%) 33	39 / 1441 (2.71%) 41
Investigations			
Blood Creatine Phosphokinase Increased			

subjects affected / exposed occurrences (all)	31 / 1441 (2.15%) 34	20 / 1445 (1.38%) 20	19 / 1441 (1.32%) 21
Blood Creatinine Increased subjects affected / exposed occurrences (all)	28 / 1441 (1.94%) 30	33 / 1445 (2.28%) 36	35 / 1441 (2.43%) 40
Blood Pressure Increased subjects affected / exposed occurrences (all)	35 / 1441 (2.43%) 44	17 / 1445 (1.18%) 18	19 / 1441 (1.32%) 22
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	34 / 1441 (2.36%) 43	38 / 1445 (2.63%) 48	36 / 1441 (2.50%) 42
Ligament Sprain subjects affected / exposed occurrences (all)	24 / 1441 (1.67%) 27	33 / 1445 (2.28%) 36	19 / 1441 (1.32%) 23
Limb Injury subjects affected / exposed occurrences (all)	33 / 1441 (2.29%) 39	31 / 1445 (2.15%) 33	26 / 1441 (1.80%) 32
Cardiac disorders			
Angina Pectoris subjects affected / exposed occurrences (all)	36 / 1441 (2.50%) 40	25 / 1445 (1.73%) 32	30 / 1441 (2.08%) 40
Atrial Fibrillation subjects affected / exposed occurrences (all)	38 / 1441 (2.64%) 42	38 / 1445 (2.63%) 48	29 / 1441 (2.01%) 35
Nervous system disorders			
Diabetic Neuropathy subjects affected / exposed occurrences (all)	40 / 1441 (2.78%) 43	34 / 1445 (2.35%) 38	41 / 1441 (2.85%) 44
Dizziness subjects affected / exposed occurrences (all)	33 / 1441 (2.29%) 41	34 / 1445 (2.35%) 40	61 / 1441 (4.23%) 85
Headache subjects affected / exposed occurrences (all)	108 / 1441 (7.49%) 155	90 / 1445 (6.23%) 111	100 / 1441 (6.94%) 137
Hypoaesthesia			

subjects affected / exposed occurrences (all)	19 / 1441 (1.32%) 21	34 / 1445 (2.35%) 37	24 / 1441 (1.67%) 26
Neuropathy Peripheral subjects affected / exposed occurrences (all)	26 / 1441 (1.80%) 27	33 / 1445 (2.28%) 38	24 / 1441 (1.67%) 25
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	55 / 1441 (3.82%) 62	41 / 1445 (2.84%) 44	40 / 1441 (2.78%) 40
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	42 / 1441 (2.91%) 46	50 / 1445 (3.46%) 59	54 / 1441 (3.75%) 73
Eye disorders Cataract subjects affected / exposed occurrences (all)	77 / 1441 (5.34%) 90	91 / 1445 (6.30%) 116	84 / 1441 (5.83%) 108
Diabetic Retinopathy subjects affected / exposed occurrences (all)	46 / 1441 (3.19%) 51	45 / 1445 (3.11%) 51	50 / 1441 (3.47%) 52
Gastrointestinal disorders Abdominal Pain subjects affected / exposed occurrences (all)	40 / 1441 (2.78%) 49	42 / 1445 (2.91%) 48	47 / 1441 (3.26%) 51
Abdominal Pain Upper subjects affected / exposed occurrences (all)	35 / 1441 (2.43%) 53	33 / 1445 (2.28%) 38	31 / 1441 (2.15%) 36
Constipation subjects affected / exposed occurrences (all)	61 / 1441 (4.23%) 68	73 / 1445 (5.05%) 84	70 / 1441 (4.86%) 81
Diarrhoea subjects affected / exposed occurrences (all)	119 / 1441 (8.26%) 168	105 / 1445 (7.27%) 133	147 / 1441 (10.20%) 195
Dyspepsia subjects affected / exposed occurrences (all)	46 / 1441 (3.19%) 52	43 / 1445 (2.98%) 51	32 / 1441 (2.22%) 35
Gastritis			

subjects affected / exposed occurrences (all)	31 / 1441 (2.15%) 33	44 / 1445 (3.04%) 53	38 / 1441 (2.64%) 40
Gastroesophageal Reflux Disease subjects affected / exposed occurrences (all)	32 / 1441 (2.22%) 34	41 / 1445 (2.84%) 42	46 / 1441 (3.19%) 48
Nausea subjects affected / exposed occurrences (all)	57 / 1441 (3.96%) 77	60 / 1445 (4.15%) 82	58 / 1441 (4.02%) 77
Toothache subjects affected / exposed occurrences (all)	31 / 1441 (2.15%) 38	38 / 1445 (2.63%) 45	32 / 1441 (2.22%) 40
Vomiting subjects affected / exposed occurrences (all)	39 / 1441 (2.71%) 45	42 / 1445 (2.91%) 49	39 / 1441 (2.71%) 45
Hepatobiliary disorders Hepatic Steatosis subjects affected / exposed occurrences (all)	32 / 1441 (2.22%) 32	18 / 1445 (1.25%) 18	20 / 1441 (1.39%) 20
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	37 / 1441 (2.57%) 49	19 / 1445 (1.31%) 24	30 / 1441 (2.08%) 32
Rash subjects affected / exposed occurrences (all)	28 / 1441 (1.94%) 37	38 / 1445 (2.63%) 50	45 / 1441 (3.12%) 51
Skin Lesion subjects affected / exposed occurrences (all)	8 / 1441 (0.56%) 9	16 / 1445 (1.11%) 24	30 / 1441 (2.08%) 37
Skin Ulcer subjects affected / exposed occurrences (all)	31 / 1441 (2.15%) 36	45 / 1445 (3.11%) 60	51 / 1441 (3.54%) 87
Renal and urinary disorders Dysuria subjects affected / exposed occurrences (all)	15 / 1441 (1.04%) 20	30 / 1445 (2.08%) 32	32 / 1441 (2.22%) 35
Pollakiuria			



subjects affected / exposed occurrences (all)	19 / 1441 (1.32%) 21	66 / 1445 (4.57%) 67	86 / 1441 (5.97%) 91
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	125 / 1441 (8.67%)	133 / 1445 (9.20%)	129 / 1441 (8.95%)
occurrences (all)	156	157	161
Back Pain			
subjects affected / exposed	137 / 1441 (9.51%)	138 / 1445 (9.55%)	149 / 1441 (10.34%)
occurrences (all)	172	190	183
Muscle Spasms			
subjects affected / exposed	52 / 1441 (3.61%)	40 / 1445 (2.77%)	52 / 1441 (3.61%)
occurrences (all)	55	46	58
Musculoskeletal Pain			
subjects affected / exposed	65 / 1441 (4.51%)	69 / 1445 (4.78%)	64 / 1441 (4.44%)
occurrences (all)	71	80	82
Myalgia			
subjects affected / exposed	43 / 1441 (2.98%)	49 / 1445 (3.39%)	36 / 1441 (2.50%)
occurrences (all)	48	58	39
Neck Pain			
subjects affected / exposed	22 / 1441 (1.53%)	20 / 1445 (1.38%)	30 / 1441 (2.08%)
occurrences (all)	26	21	31
Osteoarthritis			
subjects affected / exposed	84 / 1441 (5.83%)	83 / 1445 (5.74%)	83 / 1441 (5.76%)
occurrences (all)	96	99	91
Pain in Extremity			
subjects affected / exposed	98 / 1441 (6.80%)	105 / 1445 (7.27%)	92 / 1441 (6.38%)
occurrences (all)	114	123	127
Infections and infestations			
Bronchitis			
subjects affected / exposed	123 / 1441 (8.54%)	109 / 1445 (7.54%)	112 / 1441 (7.77%)
occurrences (all)	183	140	152
Cellulitis			
subjects affected / exposed	26 / 1441 (1.80%)	37 / 1445 (2.56%)	37 / 1441 (2.57%)
occurrences (all)	28	53	54
Conjunctivitis			

subjects affected / exposed	22 / 1441 (1.53%)	34 / 1445 (2.35%)	24 / 1441 (1.67%)
occurrences (all)	23	46	27
Cystitis			
subjects affected / exposed	23 / 1441 (1.60%)	35 / 1445 (2.42%)	34 / 1441 (2.36%)
occurrences (all)	31	48	53
Gastroenteritis			
subjects affected / exposed	42 / 1441 (2.91%)	54 / 1445 (3.74%)	43 / 1441 (2.98%)
occurrences (all)	44	60	55
Genital Infection Fungal			
subjects affected / exposed	6 / 1441 (0.42%)	19 / 1445 (1.31%)	30 / 1441 (2.08%)
occurrences (all)	6	24	40
Influenza			
subjects affected / exposed	86 / 1441 (5.97%)	100 / 1445 (6.92%)	82 / 1441 (5.69%)
occurrences (all)	115	129	105
Localised Infection			
subjects affected / exposed	26 / 1441 (1.80%)	18 / 1445 (1.25%)	30 / 1441 (2.08%)
occurrences (all)	29	21	43
Lower Respiratory Tract Infection			
subjects affected / exposed	33 / 1441 (2.29%)	32 / 1445 (2.21%)	28 / 1441 (1.94%)
occurrences (all)	64	47	62
Nasopharyngitis			
subjects affected / exposed	220 / 1441 (15.27%)	225 / 1445 (15.57%)	203 / 1441 (14.09%)
occurrences (all)	368	386	324
Pharyngitis			
subjects affected / exposed	31 / 1441 (2.15%)	43 / 1445 (2.98%)	24 / 1441 (1.67%)
occurrences (all)	37	63	26
Pneumonia			
subjects affected / exposed	39 / 1441 (2.71%)	23 / 1445 (1.59%)	39 / 1441 (2.71%)
occurrences (all)	43	24	54
Sinusitis			
subjects affected / exposed	45 / 1441 (3.12%)	58 / 1445 (4.01%)	65 / 1441 (4.51%)
occurrences (all)	64	76	94
Upper Respiratory Tract Infection			
subjects affected / exposed	163 / 1441 (11.31%)	157 / 1445 (10.87%)	133 / 1441 (9.23%)
occurrences (all)	234	231	215

Urinary Tract Infection subjects affected / exposed occurrences (all)	128 / 1441 (8.88%) 237	132 / 1445 (9.13%) 218	159 / 1441 (11.03%) 249
Viral Infection subjects affected / exposed occurrences (all)	26 / 1441 (1.80%) 30	32 / 1445 (2.21%) 35	33 / 1441 (2.29%) 40
Vulvovaginal Mycotic Infection subjects affected / exposed occurrences (all)	10 / 1441 (0.69%) 19	30 / 1445 (2.08%) 58	31 / 1441 (2.15%) 84
Metabolism and nutrition disorders			
Hyperglycaemia subjects affected / exposed occurrences (all)	91 / 1441 (6.32%) 130	55 / 1445 (3.81%) 63	63 / 1441 (4.37%) 74
Hypoglycaemia subjects affected / exposed occurrences (all)	174 / 1441 (12.07%) 1132	181 / 1445 (12.53%) 1526	210 / 1441 (14.57%) 1433

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 April 2010	The overall reason for Amendment INT-2 was to add data from completed Phase 1 studies. A summary of data that demonstrated no clinically meaningful photosensitizing potential of canagliflozin in humans was added and the photoprotective measures were removed.
11 March 2011	The overall reason for Amendment INT-3 was to were to address regulatory actions taken with rosiglitazone. Procedures for handling subjects already in the study taking rosiglitazone were added. Also, instructions were added prohibiting randomization of any subject who was taking rosiglitazone within 8 weeks before the prescreening or screening visit.
08 September 2011	The overall reasons for Amendment INT-4 were to remove the preplanned re-estimation of the sample size for Cohort B and to specify that an interim analysis of the ongoing DIA3008 study was required for reporting of safety data in the initial canagliflozin marketing applications.
13 December 2012	The overall reason for Amendment INT-5 was that the sponsor had been unblinded to the results of the analysis of the study's primary (cardiovascular) CV endpoint (major adverse cardiovascular events [MACE] events), which was part of a cross-program CV meta-analysis.
08 November 2013	The overall reason for Amendment INT-6 was to reflect the changes required for compliance with the US FDA postmarketing requirements for canagliflozin. According to these requirements, a post-approval CV meta-analysis was to occur when at least 688 MACE events (ie, CV death, nonfatal myocardial infarction [MI], nonfatal stroke) on treatment were accumulated from DIA3008 plus a planned similar study (DIA4003: A Randomized, Multicenter, Double- Blind, Parallel, Placebo-Controlled Study of the Effects of Canagliflozin on Renal Endpoints in Adult Subjects With Type 2 Diabetes Mellitus).
23 September 2015	The overall reason for Amendment INT-7 was to incorporate a request by Health Authorities to include diabetic ketoacidosis (DKA) safety information and the disposition of subjects with this event.
05 May 2016	The overall reason for Amendment INT-8 was to include new safety information and guidance regarding subject management with the event of lower-extremity amputations following a notification from the Independent Data Monitoring Committee (IDMC) regarding an increase in the lower-extremity amputation rate among study subjects in DIA3008 taking canagliflozin compared with placebo.

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported