Clinical trial results:
A 76-Week, Worldwide, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Assess the Tolerability and Efficacy of Anacetrapib When Added to Ongoing Therapy With a Statin in Patients With Coronary Heart Disease (CHD) or CHD Risk-Equivalent Disease

Summary

EudraCT number	2007-005839-28
Trial protocol	SE ES HU FR AT FI NL DE
Global end of trial date	

Results information

Result version number	v1
This version publication date	15 April 2017
First version publication date	15 April 2017

Trial information

Trial identification

Sponsor protocol code	0859-019

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00685776
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp and Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp and Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	01 July 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	No

Notes:

General information about the trial

Main objective of the trial:

This study evaluated the efficacy of anacetrapib 100 mg for 24 weeks relative to placebo, on plasma concentrations of Low Density Lipoprotein Cholesterol and assessed the 76-week safety and tolerability of anacetrapib 100mg in participants with coronary heart disease (CHD)/CHD risk equivalent disease on stable dose regimen of statin with or without other lipid-modifying therapy. The 2 year extension to this study further evaluated the long-term safety profile and efficacy of anacetrapib 100 mg in CHD/CHD-risk equivalent participants who were on ongoing therapy with a statin with or without other lipid-modifying therapy.

Protection of trial subjects:

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

Background therapy:

All participants were required to be on a stable-regimen of statin ± other lipid-modifying medication(s) for at least 6-weeks prior to enrollment.

Evidence for comparator: -

Actual start date of recruitment	24 March 2008
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	Australia: 59
Country: Number of subjects enrolled	Austria: 34
Country: Number of subjects enrolled	Canada: 62
Country: Number of subjects enrolled	Colombia: 5
Country: Number of subjects enrolled	Finland: 51
Country: Number of subjects enrolled	France: 38
Country: Number of subjects enrolled	Germany: 42
Country: Number of subjects enrolled	Hong Kong: 36
Country: Number of subjects enrolled	Hungary: 82
Country: Number of subjects enrolled	Israel: 59
Country: Number of subjects enrolled	Malaysia: 66
Country: Number of subjects enrolled	Mexico: 68
Country: Number of subjects enrolled	Netherlands: 186
Country: Number of subjects enrolled	New Zealand: 48
Country: Number of subjects enrolled	Norway: 48
Country: Number of subjects enrolled	Peru: 35
Country: Number of subjects enrolled	Russian Federation: 47

Country: Number of subjects enrolled	Spain: 93
Country: Number of subjects enrolled	Sweden: 74
Country: Number of subjects enrolled	United States: 490
Worldwide total number of subjects	1623
EEA total number of subjects	648

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	889
From 65 to 84 years	734
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Base study consisted of a 76 week treatment period and a 12-week reversal period (no treatment). The active study was extended for 2-years which was followed by a 1 year reversal (no treatment).

Pre-assignment

Screening details:

This study was enrolled participants with coronary heart disease (CHD) or CHD risk-equivalent disease that were taking a statin with or without other lipid-modifying medications. Other inclusion and exclusion criteria applied.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Anacetrapib

Arm description:

one 100-mg Anacetrapib tablet daily with food for 76 weeks administered with participant's current stable regimen of lipid-lowering therapy.

Arm type	Experimental
Investigational medicinal product name	Anacetrapib
Investigational medicinal product code	
Other name	MK-0859
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

one 100-mg tablet once daily

Arm title	Placebo

Arm description:

one placebo tablet daily with food for 76 weeks administered with participant's current stable regimen of lipid-lowering therapy.

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

Dosage and administration details:

one 100-mg tablet once daily

Number of subjects in period 1	Anacetrapib	Placebo
Started	811	812
Completed	548	663
Not completed	263	149
Physician decision	6	6
Consent withdrawn by subject	46	57
Adverse Event	46	48
LDL-C Stopping Criteria Met	142	1
Study Terminated by Sponsor	5	3
Lost to follow-up	3	13
Lack of efficacy	1	1
Protocol deviation	14	20

Period 2

Period 2 title	Base Study - Reversal (Part B)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Anacetrapib 100 mg - Base Study Reversal

Arm description:

Completers and Non-completers who received 100 mg Anacetrapib during treatment period. Participants continue with current stable regimen of lipid-lowering therapy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Placebo -Base Study Reversal

Arm description:

Completers and non-completers who received placebo in treatment period of base study. Participants continue with current stable regimen of lipid-lowering therapy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2	Anacetrapib 100 mg - Base Study Reversal	Placebo -Base Study Reversal
Started	548	663
Completed	655	690
Not completed	29	24
Unknown	29	24
Joined	136	51
non-completers from treatment phase	136	51

Period 3

Period 3 title	2-year Extension (Part C)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	No
Arm title	Anacetrapib-Extension Study

Arm description:

one 100-mg Anacetrapib tablet daily with food for 104 weeks administered with participant's current stable regimen of lipid-lowering therapy.

Arm type	Experimental
Investigational medicinal product name	Anacetrapib
Investigational medicinal product code	
Other name	MK-0859
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

one 100-mg tablet once daily

Arm title	Placebo-Extension Study

Arm description:

one placebo tablet daily with food for 104 weeks administered with participant's current stable regimen of lipid-lowering therapy.

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

Dosage and administration details:

one 100-mg tablet once daily

Number of subjects in period 3	Anacetrapib-Extension Study	Placebo-Extension Study
Started	370	433
Completed	328	386
Not completed	42	47
Physician decision	2	4
Consent withdrawn by subject	17	18
Adverse event, non-fatal	18	23
Lost to follow-up	1	1
Protocol deviation	4	-
Lack of efficacy	-	1

Period 4

Period 4 title	1-year Reversal (Part D)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	No
Arm title	Anacetrapib-1 year Reversal Study

Arm description:

Participants who received Anacetrapib 100 mg in Extension (Part C). Participants continue with current stable regimen of lipid-lowering therapy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Placebo-1 year Reversal Study

Arm description:

Participants who received placebo in Extension (Part C). Participants continue with current stable regimen of lipid-lowering therapy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 4	Anacetrapib-1 year Reversal Study	Placebo-1 year Reversal Study
Started	271	1
Completed	266	1
Not completed	5	0
Physician decision	1	-
Consent withdrawn by subject	1	-

Adverse event, non-fatal	1	-
Lost to follow-up	1	-
Progressive disease	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Anacetrapib
Reporting group description:	
one 100-mg Anacetrapib tablet daily with food for 76 weeks administered with participant's current stable regimen of lipid-lowering therapy.	
Reporting group title	Placebo
Reporting group description:	
one placebo tablet daily with food for 76 weeks administered with participant's current stable regimen of lipid-lowering therapy.	

Reporting group values	Anacetrapib	Placebo	Total
Number of subjects	811	812	1623
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	62.5	62.9	
standard deviation	± 8.7	± 9	-
Gender Categorical Units: Subjects			
Female	182	194	376
Male	629	618	1247

End points

End points reporting groups

Reporting group title	Anacetrapib
Reporting group description:	
one 100-mg Anacetrapib tablet daily with food for 76 weeks administered with participant's current stable regimen of lipid-lowering therapy.	
Reporting group title	Placebo
Reporting group description:	
one placebo tablet daily with food for 76 weeks administered with participant's current stable regimen of lipid-lowering therapy.	
Reporting group title	Anacetrapib 100 mg - Base Study Reversal
Reporting group description:	
Completers and Non-completers who received 100 mg Anacetrapib during treatment period. Participants continue with current stable regimen of lipid-lowering therapy.	
Reporting group title	Placebo -Base Study Reversal
Reporting group description:	
Completers and non-completers who received placebo in treatment period of base study. Participants continue with current stable regimen of lipid-lowering therapy.	
Reporting group title	Anacetrapib-Extension Study
Reporting group description:	
one 100-mg Anacetrapib tablet daily with food for 104 weeks administered with participant's current stable regimen of lipid-lowering therapy.	
Reporting group title	Placebo-Extension Study
Reporting group description:	
one placebo tablet daily with food for 104 weeks administered with participant's current stable regimen of lipid-lowering therapy.	
Reporting group title	Anacetrapib-1 year Reversal Study
Reporting group description:	
Participants who received Anacetrapib 100 mg in Extension (Part C). Participants continue with current stable regimen of lipid-lowering therapy.	
Reporting group title	Placebo-1 year Reversal Study
Reporting group description:	
Participants who received placebo in Extension (Part C). Participants continue with current stable regimen of lipid-lowering therapy.	
Subject analysis set title	Anacetrapib 100 mg - Base Study- Efficacy
Subject analysis set type	Full analysis
Subject analysis set description:	
All randomized participants who were not excluded due to failure to receive at least 1 dose of study treatment, lack of any post-randomization endpoint data subsequent to at least 1 dose of study treatment or lacked baseline data for those analyses that required baseline data.	
Subject analysis set title	Placebo - Base Study - Efficacy
Subject analysis set type	Full analysis
Subject analysis set description:	
All randomized participants who were not excluded due to failure to receive at least 1 dose of study treatment, lack of any post-randomization endpoint data subsequent to at least 1 dose of study treatment or lack, of baseline data for those analyses that require baseline data.	
Subject analysis set title	Anacetrapib 100 mg - Base Study - Safety
Subject analysis set type	Safety analysis
Subject analysis set description:	
All randomized participants who received at least 1 dose of study treatment in Base Study and had at least 1 post-baseline measurement for parameter assessed.	
Subject analysis set title	Placebo - Base Study- Safety
Subject analysis set type	Safety analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of study treatment in Base Study and has at least 1 post-baseline measurement for parameter assessed.

Subject analysis set title	Anacetrapib 100 mg - Extension Study - Efficacy
Subject analysis set type	Full analysis

Subject analysis set description:

All randomized participants who were not excluded due to failure to receive at least 1 dose of study treatment, lack of any post-randomization endpoint data subsequent to at least 1 dose of study treatment or lack of baseline data for those analyses that required baseline data.

Subject analysis set title	Placebo- Extension Study - Efficacy
Subject analysis set type	Full analysis

Subject analysis set description:

All randomized participants who were not excluded due to failure to receive at least 1 dose of study treatment, lack of any post-randomization endpoint data subsequent to at least 1 dose of study treatment, or lack of baseline data for those analyses that required baseline data.

Subject analysis set title	Anacetrapib 100 mg -Extension-Safety
Subject analysis set type	Safety analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of study treatment in extension and had at least 1 post-baseline measurement for parameter assessed.

Subject analysis set title	Placebo-Extension Study-Safety
Subject analysis set type	Safety analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of study treatment in Extension Study and had at least 1 post-baseline measurement for parameter assessed.

Subject analysis set title	Anacetrapib-1 year Reversal Study-Safety
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received Anacetrapib 100 mg in Extension (Part C) and had available safety data

Subject analysis set title	Placebo-1 year Reversal Study-Safety
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received placebo in Extension (Part C) and had available safety data

Primary: Percentage Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 24- Base Study

End point title	Percentage Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 24- Base Study

End point description:

LDL-C levels measured at baseline and after 24 weeks of treatment measured by Friedewald method

End point type	Primary

End point timeframe:

Baseline and Week 24

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	682	742		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-44.6 (-46.3 to -42.8)	-4.5 (-6.2 to -2.8)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1424
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis;
Parameter estimate	Difference in Least squares (LS) means
Point estimate	-40.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.4
upper limit	-37.7

Primary: Number of Participants With Hepatitis-related Adverse Events (AEs)- Base Study

End point title	Number of Participants With Hepatitis-related Adverse Events (AEs)- Base Study[1]

End point description:

An AE was defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the product, whether or not considered related to the use of the product. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition which was temporally associated with the use of the product, was also an AE. Hepatitis-related AEs were identified by a collective review using the following prespecified set of preferred terms: cholestasis, hepatic necrosis, hepatocellular damage, cytolytic hepatitis, hepatitis, hepatomegaly, jaundice, hepatic failure, hepatitis cholestatic, jaundice cholestatic, hepatitis fulminant, hyperbilirubinaemia, jaundice hepatocellular, ocular icterus, yellow skin, hepatic function abnormal, acute hepatic failure, subacute hepatic failure, hepatitis acute, hepatitis toxic, hepatotoxicity, and mixed hepatocellular-cholestatic injury.

End point type	Primary

End point timeframe:

up to 88 weeks

Notes:

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

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	808	804		
Units: Participants	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with Alanine Aminotransferase and/or Aspartate Aminotransferase Consecutive Elevations ≥ 3xULN (Upper Limit of Normal)- Treatment Phase-Base Study

End point title	Percentage of Participants with Alanine Aminotransferase and/or Aspartate Aminotransferase Consecutive Elevations ≥ 3xULN (Upper Limit of Normal)- Treatment Phase-Base Study

End point description:

Participants had alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels assessed throughout the 76 week Treatment Phase. Participants who had 2 consecutive assessments of ALT and/or AST that were 3 x ULN or greater were recorded. The ALT UNLs for males and females were 40 U/L and 33 U/L, respectively. The AST UNLs for males and females were 43 U/L and 36 U/L, respectively.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	800	796		
Units: Percentage of Participants				
number (not applicable)	0.1	1		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1596
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.019
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	-0.2

Primary: Percentage of Participants with Creatine Phosphokinase Elevations ≥10 x ULN- Treatment Phase-Base Study

End point title	Percentage of Participants with Creatine Phosphokinase Elevations ≥10 x ULN- Treatment Phase-Base Study

End point description:

Participants had creatine phosphokinase (CK) levels assessed throughout the 76 week Treatment Phase. Participants who had any CK level that was ≥ 10 x ULN were recorded. The ULNs for males and females were 207 IU/L and 169 IU/L, respectively.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	800	796		
Units: Percentage of Participants				
number (not applicable)	0	0.3		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1596
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.156
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	0.2

Primary: Percentage of Participants with Creatine Phosphokinase Elevations ≥10 x ULN with Muscle Symptoms- Treatment Phase-Base Study

End point title	Percentage of Participants with Creatine Phosphokinase Elevations ≥10 x ULN with Muscle Symptoms- Treatment Phase-Base Study

End point description:

Participants had CK levels assessed throughout the 76 week Treatment Phase. Participants who had any CK level that was ≥10 x ULN and had associated muscle symptoms present within +/- 7 days were recorded. The ULNs for males and females were 207 IU/L and 169 IU/L, respectively.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	800	796		
Units: Percentage of Participants				
number (not applicable)	0	0		

Statistical analyses

Statistical analysis title	Comparison Between Groups
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1596
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.5

Primary: Percentage of Participants with Sodium, Chloride, or Bicarbonate Elevations >ULN-Treatment Phase- Base Study

End point title	Percentage of Participants with Sodium, Chloride, or Bicarbonate Elevations >ULN-Treatment Phase- Base Study

End point description:

Participants had sodium, chloride, and bicarbonate levels assessed throughout the 76 week Treatment Phase. Participants who had any sodium level that was > the ULN of 145 mEq/L had any chloride level that was > the ULN of 110 mEq/L or had any bicarbonate level that was > the ULN of 33 mEq/L were

recorded

End point type	Primary
End point timeframe: up to 76 weeks	

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	800	796		
Units: Percentage of Participants				
number (not applicable)				
Sodium	13.9	12.9		
Chloride	3.9	4.4		
Bicarbonate	1.5	2.1		

Statistical analyses

Statistical analysis title	Comparison Between Groups - Sodium
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1596
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.584
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	4.3

Statistical analysis title	Between Group Comparison- Chloride
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1596
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.601
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	1.5

Statistical analysis title	Between Group Comparison - Bicarbonate
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1596
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.342
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	0.7

Primary: Percentage of Participants with Potassium Levels <LLN (Lower Limit of Normal)- Treatment Phase- Base Study

End point title	Percentage of Participants with Potassium Levels <LLN (Lower Limit of Normal)- Treatment Phase- Base Study

End point description:

Participants had potassium levels assessed throughout the 76 week Treatment Phase. Participants who had any potassium level that was < the LLN of 3.5 mEq/L were recorded.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	800	796		
Units: Percentage of Participants				
number (not applicable)	5	4.6		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1596
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.743
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	2.5

Primary: Percentage of Participants with Myalgia- Treatment Phase- Base Study

End point title	Percentage of Participants with Myalgia- Treatment Phase- Base Study

End point description:

Adverse events were recorded throughout the 76 week Treatment Phase. The percentage of participants who experienced an AE reported with verbatim term "myalgia" were summarized.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	808	804		
Units: Percentage of Participants				
number (not applicable)	4	3.5		

Statistical analyses

Statistical analysis title	Comparison Between Groups
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety

Number of subjects included in analysis	1612
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.612
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	2.4

Primary: Percentage of Participants with Rhabdomyolysis- Treatment Phase- Base Study

End point title	Percentage of Participants with Rhabdomyolysis- Treatment Phase- Base Study

End point description:

Adverse events were recorded throughout the 76 week Treatment Phase. The percentage of participants who experienced an AE reported with verbatim term "rhabdomyolysis" were summarized.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	808	804		
Units: Percentage of Participants				
number (not applicable)	0	0		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1612
Analysis specification	Pre-specified
Analysis type	other
P-value	> 0.999
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	0.5

Primary: Percentage of Participants with Prespecified Adjudicated Cardiovascular Serious Adverse Events (SAEs)- Treatment Phase- Base Study

End point title	Percentage of Participants with Prespecified Adjudicated Cardiovascular Serious Adverse Events (SAEs)- Treatment Phase- Base Study

End point description:

Participants who experienced the SAEs of CV death, Non-fatal stroke, non-fatal myocardial infarction, or unstable angina during the 76 week Treatment Phase were recorded. These cardiovascular events that occurred during the Base Study were adjudicated by an expert committee external to the sponsor.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	808	804		
Units: Percentage of Participants				
number (not applicable)	1.6	2.6		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1612
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.161
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	0.4

Primary: Percentage of Participants with Death from Any Cause- Treatment Phase- Base Study

End point title	Percentage of Participants with Death from Any Cause- Treatment Phase- Base Study
End point description: Participants who died from any cause during the 76 week Treatment Phase were recorded. All deaths were adjudicated by an expert committee independent of the Sponsor.	
End point type	Primary
End point timeframe: up to 76 weeks	

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	808	804		
Units: Percentage of Participants				
number (not applicable)	0.7	0.9		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1612
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.774
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	0.8

Primary: Percentage of Participants with Alanine Aminotransferase and/or Aspartate Aminotransferase Consecutive Elevations ≥ 3xULN (Upper Limit of Normal)- Extension Study

End point title	Percentage of Participants with Alanine Aminotransferase and/or Aspartate Aminotransferase Consecutive Elevations ≥ 3xULN (Upper Limit of Normal)- Extension Study

End point description:

Participants had alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels assessed throughout the 104 week Extension Study. Participants who had 2 consecutive assessments of ALT and/or AST that were 3 x ULN or greater were recorded. The ALT UNLs for males and females were 40 U/L and 33 U/L, respectively.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	433		
Units: Percentage of Participants				
number (not applicable)	0.3	0.9		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	0.7

Primary: Percentage of Participants with Creatine Phosphokinase Elevations ≥10xULN- Extension Study

End point title	Percentage of Participants with Creatine Phosphokinase Elevations ≥10xULN- Extension Study

End point description:

Participants had creatine phosphokinase (CK) levels assessed throughout the 104 week Extension Study. Participants who had any CK level that was >=10 x ULN were recorded. The ULNs for males and females were 207 IU/L and 169 IU/L, respectively.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	433		
Units: Percentage of Participants				
number (not applicable)	0	0		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	1

Primary: Percentage of Participants with Creatine Phosphokinase Elevations ≥10xULN with Muscle Symptoms- Extension Study

End point title	Percentage of Participants with Creatine Phosphokinase Elevations ≥10xULN with Muscle Symptoms- Extension Study

End point description:

Participants had CK levels assessed throughout the 104 week Extension Study. Participants who had any CK level that was ≥10 x ULN and had associated muscle symptoms present within +/- 7 days were recorded. The ULNs for males and females were 207 IU/L and 169 IU/L, respectively.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	433		
Units: Percentage of Participants				
number (not applicable)	0	0		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	1

Primary: Percentage of Participants with Sodium, Chloride, or Bicarbonate Elevations >ULN- Extension Study

End point title	Percentage of Participants with Sodium, Chloride, or Bicarbonate Elevations >ULN- Extension Study

End point description:

Participants had sodium, chloride, and bicarbonate levels assessed throughout the 104 week Extension Study. Participants who had any sodium level that was > the ULN of 145 mEq/L had any chloride level that was > the ULN of 110 mEq/L or had any bicarbonate level that was > the ULN of 33 mEq/L were recorded

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	433		
Units: Percentage of Participants				
number (not applicable)				
Sodium	7.1	5.3		

Chloride	1.4	0.5		
Bicarbonate	1.4	1.4		

Statistical analyses

Statistical analysis title	Between Group Comparison- Sodium
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	5.4

Statistical analysis title	Between Group Comparison- Chloride
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	2.7

Statistical analysis title	Between Group Comparison- Bicarbonate
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	799
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	1.9

Primary: Percentage of Participants with Potassium Levels <LLN (Lower Limit of Normal)- Extension Study

End point title	Percentage of Participants with Potassium Levels <LLN (Lower Limit of Normal)- Extension Study

End point description:

Participants had potassium levels assessed throughout the 104 week Extension Study. Participants who had any potassium level that was < the LLN of 3.5 mEq/L were recorded.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg -Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	432		
Units: Percentage of Participants				
number (not applicable)	2.2	3		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	798
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	1.6

Primary: Percentage of Participants with Myalgia- Extension Study

End point title	Percentage of Participants with Myalgia- Extension Study

End point description:

Adverse events were recorded throughout the 104 week Extension Study. The number of participants who experienced an AE reported with verbatim term "myalgia" were summarized.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg -Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	369	433		
Units: Percentage of Participants				
number (not applicable)	1.6	2.5		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	802
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.371
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	1.2

Primary: Percentage of Participants with Rhabdomyolysis- Extension Study

End point title	Percentage of Participants with Rhabdomyolysis- Extension Study

End point description:

Adverse events were recorded throughout the 104 week Extension Study. The number of participants who experienced an AE reported with verbatim term "rhabdomyolysis" were summarized.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	369	433		
Units: Percentage of Participants				
number (not applicable)	0	0.2		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	802
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.356
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	0.8

Primary: Percentage of Participants with Prespecified Adjudicated Cardiovascular Serious Adverse Events (SAEs)- Extension Study

End point title	Percentage of Participants with Prespecified Adjudicated Cardiovascular Serious Adverse Events (SAEs)- Extension Study

End point description:

Participants who experienced the SAEs of cardiovascular (CV) death, Non-fatal stroke, non-fatal myocardial infarction, or unstable angina during the 104 week Extension Study were recorded. These cardiovascular events that occurred during the Base Study were adjudicated by an expert committee external to the sponsor.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	370	433		
Units: Percentage of Participants				
number (not applicable)	3.8	3.2		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	3.3

Primary: Percentage of Participants with Death from Any Cause- Extension Study

End point title	Percentage of Participants with Death from Any Cause-Extension Study

End point description:

Participants who died from any cause during the 104 week Extension Study were recorded. All deaths were adjudicated by an expert committee independent of the Sponsor.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	370	433		
Units: Percentage of Participants				
number (not applicable)	2.4	2.1		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	803
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	2.7

Primary: Percentage of Participants Who Experience at Least 1 AE- 1 year Reversal Study

End point title	Percentage of Participants Who Experience at Least 1 AE- 1 year Reversal Study[2]

End point description:

An AE was defined as any untoward medical occurrence in a subject which does not necessarily have a causal relationship with the treatment. An AE was any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with use of a medicinal product, whether or not considered related to the medicinal product. Note: An interactive voice response system (IVRS) distribution error resulted in only 1 participant who received placebo during the 2-year extension enrolled in the 1-year reversal phase instead of the approximately 68 placebo participants that were planned. All participants who had received anacetrapib 100 mg during the 2 year extension enrolled as planned in the 1-year reversal phase. Thus no comparative analysis was performed on data from the 1-year reversal phase.

End point type	Primary

End point timeframe:

up to 52 weeks

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: An error with the IVRS during enrollment resulted in only 1 placebo participant being enrolled. Planned statistical analysis was not performed.

End point values	Anacetrapib-1 year Reversal Study-Safety	Placebo-1 year Reversal Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	271	1		
Units: Percentage of Participants				
number (not applicable)	49.4	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Who Experience at Least 1 Drug-related AE- 1 year Reversal Study

End point title	Percentage of Participants Who Experience at Least 1 Drug-related AE- 1 year Reversal Study[3]

End point description:

An AE was defined as any untoward medical occurrence in a subject which does not necessarily have a causal relationship with the treatment. An AE was any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with use of a medicinal product, whether or not considered related to the medicinal product. Adverse events reported as at least possibly related to study drug were summarized. Note: An IVRS distribution error resulted in only 1 participant who received placebo during the 2-year extension enrolled in the 1-year reversal phase instead of the approximately 68 placebo participants that were planned. All participants who had received anacetrapib 100 mg during the 2 year extension enrolled as planned in the 1-year reversal phase. Thus no comparative analysis was performed on data from the 1-year reversal phase.

End point type	Primary

End point timeframe:

up to 52 weeks

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: An error with the IVRS during enrollment resulted in only 1 placebo participant being enrolled. Planned statistical analysis was not performed.

End point values	Anacetrapib-1 year Reversal Study-Safety	Placebo-1 year Reversal Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	271	1		
Units: Percentage of Participants				
number (not applicable)	1.5	0		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Sodium at Week 76-Base Study

End point title	Change From Baseline in Sodium at Week 76-Base Study

End point description:

Sodium levels were assessed at baseline and after 76 weeks of treatment. The change from baseline was recorded.

End point type	Primary

End point timeframe:

Baseline and Week 76

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	551	662		
Units: mEq/L				
least squares mean (confidence interval	-1 (-1.2 to	-1.3 (-1.5 to		

95%)	-0.8)	-1.1)

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1213
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.019
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.5

Primary: Change From Baseline in Chloride at Week 76-Base Study

End point title	Change From Baseline in Chloride at Week 76-Base Study
End point description:	
Chloride levels were assessed at baseline and after 76 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	551	662		
Units: mEq/L				
least squares mean (confidence interval 95%)	-1.8 (-2 to -1.5)	-1.9 (-2.1 to -1.7)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1213
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.414
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.4

Primary: Change From Baseline in Bicarbonate at Week 76-Base Study	
End point title	Change From Baseline in Bicarbonate at Week 76-Base Study
End point description:	
Bicarbonate levels were assessed at baseline and after 76 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	552	664		
Units: mEq/L				
least squares mean (confidence interval 95%)	0.2 (0 to 0.4)	0.3 (0.1 to 0.5)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety

Number of subjects included in analysis	1216
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.791
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.2

Primary: Change From Baseline in Potassium at Week 76-Base Study

End point title	Change From Baseline in Potassium at Week 76-Base Study
End point description:	
Potassium levels were assessed at baseline and after 76 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	549	657		
Units: mEq/L				
least squares mean (confidence interval 95%)	-0.1 (-0.1 to -0.1)	-0.1 (-0.1 to -0.1)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1206
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.282
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0

Primary: Percentage of Participants With Elevations in Systolic Blood Pressure (SBP) ≥ 10 mm Hg-Treatment Phase- Base Study

End point title	Percentage of Participants With Elevations in Systolic Blood Pressure (SBP) ≥ 10 mm Hg-Treatment Phase- Base Study

End point description:

Participants had SBP assessed at baseline and throughout the 76 week Treatment Phase. Participants who had a SBP reading that was ≥ 10 mm Hg higher than their baseline level for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	801	796		
Units: Percentage of Participants				
number (not applicable)	62.5	64.8		

Statistical analyses

Statistical analysis title	Between Group comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1597
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.344
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	2.4

Primary: Percentage of Participants With Elevations in SBP ≥ 15 mm Hg- Treatment Phase- Base Study

End point title	Percentage of Participants With Elevations in SBP ≥ 15 mm Hg-Treatment Phase- Base Study

End point description:

Participants had SBP assessed throughout the 76 week Treatment Phase. Participants who had a SBP reading that was ≥ 15 mm Hg higher than their baseline level for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	801	796		
Units: Percentage of Participants				
number (not applicable)	44.2	47.4		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1597
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.204
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	-3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	1.7

Primary: Percentage of Participants With Elevations in Diastolic Blood Pressure (DBP) ≥ 10 mm Hg-Treatment Phase- Base Study

End point title	Percentage of Participants With Elevations in Diastolic Blood Pressure (DBP) ≥ 10 mm Hg-Treatment Phase- Base Study

End point description:

Participants had DBP assessed throughout the 76 week Treatment Phase. Participants who had a DBP reading that was ≥ 10 mm Hg higher than their baseline level for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:

up to 76 weeks

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	801	796		
Units: Percentage of Participants				
number (not applicable)	40.4	39.9		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1597
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.839
Method	Miettinen and Nurminen
Parameter estimate	Difference in Percentages
Point estimate	0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	5.3

Primary: Change From Baseline in SBP at Week 76-Base Study

End point title	Change From Baseline in SBP at Week 76-Base Study
End point description:	
Participants had SBP measured at baseline and after 76 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	551	665		
Units: mmHg				
least squares mean (confidence interval 95%)	2.2 (1 to 3.3)	2.1 (1 to 3.1)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1216
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.896
Method	Miettinen and Nurminen
Parameter estimate	Difference in Least-squares Means
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	1.6

Primary: Change From Baseline in DBP at Week 76-Base Study

End point title	Change From Baseline in DBP at Week 76-Base Study
End point description:	
Participants had DBP measured at baseline and after 76 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study - Safety	Placebo - Base Study- Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	551	665		
Units: mmHg				
least squares mean (confidence interval 95%)	0.7 (0 to 1.3)	0.7 (0.1 to 1.3)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study - Safety v Placebo - Base Study- Safety
Number of subjects included in analysis	1216
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.87
Method	Miettinen and Nurminen
Parameter estimate	Difference in Least-squares Means
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	0.8

Primary: Change from Baseline in Sodium at Week 104-Extension Study

End point title	Change from Baseline in Sodium at Week 104-Extension Study
End point description:	
Sodium levels were assessed at baseline and after 104 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 104	

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	308	359		
Units: mEq/L				
least squares mean (confidence interval 95%)	-0.3 (-0.5 to -0.1)	-0.3 (-0.5 to -0.1)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	667
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.3

Primary: Change From Baseline in Chloride at Week 104-Extension Study	
End point title	Change From Baseline in Chloride at Week 104-Extension Study
End point description:	
Chloride levels were assessed at baseline and after 104 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 104	

End point values	Anacetrapib 100 mg -Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	308	359		
Units: mEq/L				
least squares mean (confidence interval 95%)	-1.9 (-2.2 to -1.6)	-2.1 (-2.4 to -1.8)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	667
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.5

Primary: Change From Baseline in Bicarbonate at Week 104-Extension Study

End point title	Change From Baseline in Bicarbonate at Week 104-Extension Study

End point description:

Bicarbonate levels were assessed at baseline and after 104 weeks of treatment. The change from baseline was recorded.

End point type	Primary

End point timeframe:

Baseline and Week 104

End point values	Anacetrapib 100 mg -Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	308	359		
Units: mEq/L				
least squares mean (confidence interval 95%)	0.2 (0 to 0.5)	0.2 (0 to 0.5)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	667
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	0.4

Primary: Change From Baseline in Potassium at Week 104-Extension Study

End point title	Change From Baseline in Potassium at Week 104-Extension Study

End point description:

Potassium levels were assessed at baseline and after 104 weeks of treatment. The change from baseline was recorded.

End point type	Primary

End point timeframe:

Baseline and Week 104

End point values	Anacetrapib 100 mg -Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	308	359		
Units: mEq/L				
least squares mean (confidence interval 95%)	0 (-0.1 to 0)	-0.1 (-0.1 to -0.1)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	667
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0.1

Primary: Percentage of Participants With Elevations in SBP ≥ 10 mmHg-Extension Study

End point title	Percentage of Participants With Elevations in SBP ≥ 10 mmHg-Extension Study

End point description:

Participants had SBP assessed at baseline and throughout the 104 week Extension Study. Participants who had a SBP reading that was ≥ 10 mm Hg higher than their baseline level for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	432		
Units: Percentage of Participants				
number (not applicable)	63.9	59.7		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	798
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	10.9

Primary: Percentage of Participants With Elevations in SBP ≥ 15mm Hg-Extension Study

End point title	Percentage of Participants With Elevations in SBP ≥ 15mm Hg-Extension Study

End point description:

Participants had SBP assessed at baseline and throughout the 104 week Extension Study. Participants who had a SBP reading that was ≥ 15 mm Hg higher than their baseline level for any assessment performed during the treatment period were recorded.

End point type	Primary

End point timeframe:

up to 104 weeks

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	432		
Units: Percentage of Participants				
number (not applicable)	49.7	45.8		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	798
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	10.8

Primary: Percentage of Participants With Elevations in DBP ≥ 10 mm Hg-Extension Study

End point title	Percentage of Participants With Elevations in DBP ≥ 10 mm Hg-Extension Study
End point description:	
Participants had DBP assessed at baseline and throughout the 104 week Extension Study. Participants who had a DBP reading that was ≥ 10 mm Hg higher than their baseline level for any assessment performed during the treatment period were recorded.	
End point type	Primary
End point timeframe:	
up to 104 weeks	

End point values	Anacetrapib 100 mg - Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	366	432		
Units: Percentage of Participants				
number (not applicable)	38	33.8		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	798
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Percentages
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	10.9

Primary: Change From Baseline in SBP at Week 104-Extension Study	
End point title	Change From Baseline in SBP at Week 104-Extension Study
End point description:	
Participants had SBP measured at baseline and after 104 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 104	

End point values	Anacetrapib 100 mg -Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	313	361		
Units: mmHg				
least squares mean (confidence interval 95%)	2.8 (1.2 to 44)	2.1 (0.6 to 3.6)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety

Number of subjects included in analysis	674
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	2.7

Primary: Change From Baseline in DBP at Week 104-Extension Study

End point title	Change From Baseline in DBP at Week 104-Extension Study
End point description:	
Participants had DBP measured at baseline and after 104 weeks of treatment. The change from baseline was recorded.	
End point type	Primary
End point timeframe:	
Baseline and Week 104	

End point values	Anacetrapib 100 mg -Extension-Safety	Placebo-Extension Study-Safety		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	313	361		
Units: mmHg				
least squares mean (confidence interval 95%)	-0.1 (-1 to 0.9)	-0.9 (-1.8 to -0.1)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg -Extension-Safety v Placebo-Extension Study-Safety
Number of subjects included in analysis	674
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	2.1

Secondary: Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 24- Base Study

End point title	Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 24- Base Study
End point description:	
HDL-C levels measured at baseline and after 24 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	685	744		
Units: Percentage Change				
least squares mean (confidence interval 95%)	153 (149.9 to 156.2)	14.6 (11.6 to 17.7)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1429
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	138.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	134.2
upper limit	142.6

Secondary: Percentage Change from Baseline in Non-High Density Lipoprotein Cholesterol at Week 24- Base Study

End point title	Percentage Change from Baseline in Non-High Density Lipoprotein Cholesterol at Week 24- Base Study

End point description:	
Non-HDL-C measured at baseline and after 24 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	685	744		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-36.1 (-37.5 to -34.7)	-4.1 (-5.5 to -2.8)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1429
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	-31.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.8
upper limit	-30

Secondary: Percentage Change from Baseline in Apolipoprotein B at Week 24- Base Study

End point title	Percentage Change from Baseline in Apolipoprotein B at Week 24- Base Study
End point description:	
Apolipoprotein B was measured at baseline and after 24 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	769	767		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-19.1 (-20.4 to -17.8)	2 (0.7 to 3.3)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1536
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	-21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.8
upper limit	-19.4

Secondary: Percentage Change from Baseline in Apolipoprotein A-1 at Week 24- Base Study

End point title	Percentage Change from Baseline in Apolipoprotein A-1 at Week 24- Base Study
End point description:	
Apolipoprotein A-1 measured at baseline and after 24 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 24	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	769	767		
Units: Percentage Change				
least squares mean (confidence interval 95%)	47.5 (46.1 to 48.9)	2.8 (1.4 to 4.2)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1536
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	44.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.8
upper limit	46.6

Secondary: Percentage Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 76- Base Study

End point title	Percentage Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 76- Base Study
End point description:	
LDL-C levels measured at baseline and after 76 weeks of treatment measured by Friedewald method	
End point type	Secondary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	543	665		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-40.5 (-42.5 to -38.6)	-4.4 (-6.2 to -2.6)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1208
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis;
Parameter estimate	Difference in Least-squares Means
Point estimate	-36.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.7
upper limit	-33.5

Secondary: Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 76- Base Study

End point title	Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 76- Base Study
End point description:	
HDL-C measured at baseline and after 76 week of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	548	666		
Units: Percentage Change				
least squares mean (confidence interval 95%)	151.2 (148 to 154.3)	12.2 (9.2 to 15.3)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy

Number of subjects included in analysis	1214
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	138.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	134.7
upper limit	143.2

Secondary: Percentage Change from Baseline in Non-high Density Lipoprotein Cholesterol at Week 76- Base Study

End point title	Percentage Change from Baseline in Non-high Density Lipoprotein Cholesterol at Week 76- Base Study
End point description:	
Non-HDL-C measured at baseline and after 76 week of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	548	666		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-33.1 (-34.8 to -31.5)	-3.8 (-5.3 to -2.2)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1214
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	-29.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.5
upper limit	-27.1

Secondary: Percentage Change from Baseline in Apolipoprotein B at Week 76- Base Study

End point title	Percentage Change from Baseline in Apolipoprotein B at Week 76- Base Study
End point description:	
Apolipoprotein B measured at baseline and after 76 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	572	670		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-20.6 (-22.1 to -19.1)	-2.3 (-3.7 to -0.9)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	-18.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.2
upper limit	-16.4

Secondary: Percentage Change from Baseline in Apolipoprotein A-1 at Week 76- Base Study

End point title	Percentage Change from Baseline in Apolipoprotein A-1 at Week 76- Base Study
End point description:	
Apolipoprotein A-1 measured at baseline and after 76 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 76	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	572	670		
Units: Percentage Change				
least squares mean (confidence interval 95%)	41.8 (40.4 to 43.2)	-0.5 (-1.8 to 0.9)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1242
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Constrained Longitudinal Data Analysis
Parameter estimate	Difference in Least-squares Means
Point estimate	42.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.4
upper limit	44.1

Secondary: Percentage Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 88- Base Study

End point title	Percentage Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 88- Base Study
End point description:	
LDL-C measured at baseline and at Week 88 (76 weeks treatment then 12 week reversal [no treatment])	
End point type	Secondary

End point timeframe: Baseline and Week 88

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	641	681		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-24.5 (-26.6 to -22.4)	-5.9 (-7.9 to -3.9)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1322
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	-18.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.5
upper limit	-15.7

Secondary: Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 88- Base Study

End point title	Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 88- Base Study
End point description: HDL-C measured at baseline and at Week 88 (76 weeks treatment then 12 week reversal [no treatment])	
End point type	Secondary
End point timeframe: Baseline and Week 88	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	655	685		
Units: Percentage Change				
least squares mean (confidence interval 95%)	87.1 (84.6 to 89.7)	14.1 (11.6 to 16.6)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1340
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	73
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.4
upper limit	76.6

Secondary: Percentage Change from Baseline in Non-High Density Lipoprotein Cholesterol at Week 88- Base Study

End point title	Percentage Change from Baseline in Non-High Density Lipoprotein Cholesterol at Week 88- Base Study
End point description:	
Non-HDL-C measured at baseline and at Week 88 (76 weeks treatment then 12 week reversal [no treatment])	
End point type	Secondary
End point timeframe:	
Baseline and Week 88	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	655	685		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-21.8 (-23.6 to -20)	-4.2 (-6 to -2.5)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1340
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	-17.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20
upper limit	-15.1

Secondary: Percentage Change from Baseline in Apolipoprotein B at Week 88- Base Study

End point title	Percentage Change from Baseline in Apolipoprotein B at Week 88- Base Study
End point description:	
Apolipoprotein B measured at baseline and at Week 88 (76 weeks treatment then 12 week reversal [no treatment])	
End point type	Secondary
End point timeframe:	
Baseline and Week 88	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	651	677		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-14.9 (-16.4 to -13.4)	-4.7 (-6.2 to -3.2)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1328
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	-10.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.3
upper limit	-8.1

Secondary: Percentage Change from Baseline in Apolipoprotein A-1 at Week 88- Base Study

End point title	Percentage Change from Baseline in Apolipoprotein A-1 at Week 88- Base Study
End point description:	
Apolipoprotein A-1 measured at baseline and at Week 88 (76 weeks treatment then 12 week reversal [no treatment])	
End point type	Secondary
End point timeframe:	
Baseline and Week 88	

End point values	Anacetrapib 100 mg - Base Study- Efficacy	Placebo - Base Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	651	677		
Units: Percentage Change				
least squares mean (confidence interval 95%)	21.7 (20.6 to 22.9)	-2.8 (-3.9 to -1.6)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Base Study- Efficacy v Placebo - Base Study - Efficacy
Number of subjects included in analysis	1328
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	24.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	22.9
upper limit	26.1

Secondary: Percentage Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 104- Extension Study

End point title	Percentage Change From Baseline in Low-Density Lipoprotein Cholesterol (LDL-C) at Week 104- Extension Study
End point description:	
LDL-C levels measured at baseline and after 104 weeks of treatment measured by Friedewald method	
End point type	Secondary
End point timeframe:	
Baseline and Week 104 of Extension Study	

End point values	Anacetrapib 100 mg - Extension Study - Efficacy	Placebo- Extension Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	308	361		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-45.2 (-48.2 to -42.3)	-5.4 (-8.1 to -2.6)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Extension Study - Efficacy v Placebo- Extension Study - Efficacy
Number of subjects included in analysis	669
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	-39.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.8
upper limit	-36

Secondary: Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 104- Extension Study

End point title	Percentage Change from Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 104- Extension Study
End point description: HDL-C levels measured at baseline and after 104 weeks of treatment.	
End point type	Secondary
End point timeframe: Baseline and week 104 of Extension	

End point values	Anacetrapib 100 mg - Extension Study - Efficacy	Placebo- Extension Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	310	361		
Units: Percentage Change				
least squares mean (confidence interval 95%)	169.3 (165 to 173.7)	15.8 (11.7 to 19.8)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Extension Study - Efficacy v Placebo- Extension Study - Efficacy
Number of subjects included in analysis	671
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	153.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	147.9
upper limit	159.2

Secondary: Percentage Change from Baseline in Non-High Density Lipoprotein Cholesterol at Week 104- Extension Study

End point title	Percentage Change from Baseline in Non-High Density Lipoprotein Cholesterol at Week 104- Extension Study
End point description: Non-HDL-C levels measured at baseline and after 104 weeks of treatment.	
End point type	Secondary
End point timeframe: Baseline and Week 104 of Extension Study	

End point values	Anacetrapib 100 mg - Extension Study - Efficacy	Placebo-Extension Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	310	361		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-35.5 (-38.1 to -33)	-4.6 (-7 to -2.3)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Extension Study - Efficacy v Placebo-Extension Study - Efficacy
Number of subjects included in analysis	671
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares means
Point estimate	-30.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.2
upper limit	-27.5

Secondary: Percentage Change from Baseline in Apolipoprotein B at Week 104-Extension Study

End point title	Percentage Change from Baseline in Apolipoprotein B at Week 104- Extension Study
End point description:	
Apolipoprotein B levels measured at baseline and after 104 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 104 of Extension Study	

End point values	Anacetrapib 100 mg - Extension Study - Efficacy	Placebo- Extension Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	310	358		
Units: Percentage Change				
least squares mean (confidence interval 95%)	-30.6 (-32.6 to -28.6)	-14.3 (-16.2 to -12.4)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Extension Study - Efficacy v Placebo- Extension Study - Efficacy
Number of subjects included in analysis	668
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	-16.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.9
upper limit	-13.7

Secondary: Percentage Change from Baseline in Apolipoprotein A-1 at Week 104- Extension Study

End point title	Percentage Change from Baseline in Apolipoprotein A-1 at Week 104- Extension Study
End point description:	
Apolipoprotein A-1 levels measured at baseline and after 104 weeks of treatment.	
End point type	Secondary
End point timeframe:	
Baseline and Week 104 of Extension Study	

End point values	Anacetrapib 100 mg - Extension Study - Efficacy	Placebo- Extension Study - Efficacy		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	310	358		
Units: Percentage Change				
least squares mean (confidence interval 95%)	41.8 (39.5 to 44.1)	-2.7 (-4.8 to -0.5)		

Statistical analyses

Statistical analysis title	Between Group Comparison
Comparison groups	Anacetrapib 100 mg - Extension Study - Efficacy v Placebo-Extension Study - Efficacy
Number of subjects included in analysis	668
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Difference in Least-squares Means
Point estimate	44.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.6
upper limit	47.4

Adverse events information

Timeframe for reporting adverse events:

Base Study-Treatment Phase-up to 76 weeks; Reversal Phase-up to 12 weeks; Post-study Phase- up to 24 weeks. Extension Study-up to 104 weeks. Reversal Study-up to 52 weeks

Adverse event reporting additional description:

AE additional description

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	Placebo-Reversal Phase-Base Study

Reporting group description:

Participants, who received at least 1 dose of Placebo in Treatment Phase of Base Study, started Reversal Phase of Base Study and had available safety data.

Reporting group title	Placebo-Treatment Phase-Base Study

Reporting group description:

Participants who received at least 1 dose of placebo in Treatment Phase of Base Study and had available safety data.

Reporting group title	Anacetrapib 100 mg-Treatment Phase-Base Study

Reporting group description:

Participants who received at least 1 dose of Anacetrapib in Treatment Phase of Base Study and had available safety data.

Reporting group title	Anacetrapid 100 mg-Reversal Phase-Base Study

Reporting group description:

-Participants, who received at least 1 dose of Anacetrapib in Treatment Phase of Base Study, started Reversal Phase of Base Study and had available safety data.

Reporting group title	Placebo-Post Treatment Phase-Base Study

Reporting group description:

Participant enrolled in Base Study who received at least 1 dose of Placebo in Treatment Phase of Base Study and had available safety data. Post Treatment period was period from end of Reversal Phase up to start of 2–year extension.

Reporting group title	Anacetrapib 100 mg-Post Treatment Phase-Base Study

Reporting group description:

Participant enrolled in Base Study who received at least 1 dose of Anacetrapib in Treatment Phase of Base Study and had available safety data. Post Treatment period was period from end of Reversal Phase up to start of 2–year extension.

Reporting group title	Anacetrapib-2-year Extension Study

Reporting group description:

Participants who were enrolled in 2-year extension, received at least 1 dose of Anacetrapib and had available safety data.

Reporting group title	Placebo-2-year Extension Study

Reporting group description:

Participants who were enrolled in 2-year extension, received at least 1 dose of placebo and had available safety data.

Reporting group title	Anacetrapib-1-year Reversal Study

Reporting group description:

Participants who were enrolled in 1-year reversal, received at least 1 dose of Anacetrapib in the extension and had available safety data.

Reporting group title	Placebo-1-year Reversal Study

Reporting group description:

Participants who were enrolled in 1-year reversal, received at least 1 dose of Placebo in the extension

Serious adverse events	Placebo-Reversal Phase-Base Study	Placebo-Treatment Phase-Base Study	Anacetrapib 100 mg-Treatment Phase-Base Study
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 714 (2.66%)	118 / 804 (14.68%)	112 / 808 (13.86%)
number of deaths (all causes)	1	7	6
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign gastric neoplasm			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 neoplasm			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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

Breast cancer			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Colon cancer			
subjects affected / exposed	1 / 714 (0.14%)	1 / 804 (0.12%)	0 / 808 (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
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant melanoma			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			

subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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 renal cell carcinoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Prostate cancer			
subjects affected / exposed	0 / 714 (0.00%)	4 / 804 (0.50%)	0 / 808 (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
Prostate cancer stage II			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 cancer			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma stage III			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			

subjects affected / exposed	1 / 714 (0.14%)	1 / 804 (0.12%)	0 / 808 (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 skin			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	3 / 808 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic squamous cell carcinoma			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat cancer			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular melanoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma metastatic			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian adenoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid cancer			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage IV			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma multiforme			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery aneurysm			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			

subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
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 aneurysm rupture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 714 (0.14%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	1 / 714 (0.14%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Non-cardiac chest pain			

subjects affected / exposed	1 / 714 (0.14%)	5 / 804 (0.62%)	6 / 808 (0.74%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Sudden death			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Thrombosis in device			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Electrocution			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatism			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Oropharyngeal pain			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 714 (0.14%)	1 / 804 (0.12%)	0 / 808 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			

Depression			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid bruit			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 bones fracture			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	0 / 808 (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
Fibula fracture			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus lesion			

subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Radius fracture			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	0 / 808 (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
Rib fracture			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
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 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat stroke			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic pain			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 714 (0.00%)	6 / 804 (0.75%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina pectoris			
subjects affected / exposed	1 / 714 (0.14%)	11 / 804 (1.37%)	5 / 808 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 11	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 714 (0.00%)	3 / 804 (0.37%)	3 / 808 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 714 (0.14%)	4 / 804 (0.50%)	5 / 808 (0.62%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure congestive			
subjects affected / exposed	1 / 714 (0.14%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			

subjects affected / exposed	0 / 714 (0.00%)	4 / 804 (0.50%)	5 / 808 (0.62%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 714 (0.00%)	3 / 804 (0.37%)	4 / 808 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Myocardial ischaemia			
subjects affected / exposed	0 / 714 (0.00%)	3 / 804 (0.37%)	0 / 808 (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
Palpitations			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			

subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (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
Supraventricular tachycardia			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
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 fibrillation			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal rhythm			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain injury			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 714 (0.00%)	4 / 804 (0.50%)	4 / 808 (0.50%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Multiple system atrophy			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal nerve palsy			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post herpetic neuralgia			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 714 (0.00%)	3 / 804 (0.37%)	5 / 808 (0.62%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	0 / 808 (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
Vocal cord paralysis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow oedema			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
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 disorders			
Cataract			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal fissure			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic polyp			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 714 (0.00%)	3 / 804 (0.37%)	0 / 808 (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
Diarrhoea			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	1 / 714 (0.14%)	1 / 804 (0.12%)	0 / 808 (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
Gastritis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			

subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	3 / 808 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal symptom			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gastroparesis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal vascular malformation			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia, obstructive			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			

subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
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 necrosis			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemobilia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytoclastic vasculitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar pain			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 failure acute			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Carcinoid syndrome			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Hyperparathyroidism			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	0 / 808 (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
Costochondritis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	4 / 808 (0.50%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 osteoarthritis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	1 / 714 (0.14%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	0 / 808 (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
Cellulitis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Lobar pneumonia			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 infection			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal abscess			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 714 (0.14%)	2 / 804 (0.25%)	3 / 808 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 714 (0.00%)	2 / 804 (0.25%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon gangrene			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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	0 / 714 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 714 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 714 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Anacetrapid 100 mg-Reversal Phase-Base Study	Placebo-Post Treatment Phase-Base Study	Anacetrapib 100 mg-Post Treatment Phase-Base Study
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 684 (3.07%)	24 / 804 (2.99%)	34 / 808 (4.21%)
number of deaths (all causes)	1	5	7
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign gastric neoplasm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 tract adenoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip neoplasm malignant stage unspecified			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to lung			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Prostate cancer			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage II			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma stage III			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	1 / 684 (0.15%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			

subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bowen's disease			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Throat cancer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular melanoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma metastatic			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to bone			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian adenoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid cancer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage IV			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma multiforme			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dissection			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery aneurysm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery stenosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombophlebitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	3 / 808 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Non-cardiac chest pain			
subjects affected / exposed	1 / 684 (0.15%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis in device			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocution			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatism			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Uterine prolapse			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 obstructive pulmonary disease			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1

Acute respiratory failure			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis chronic			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid bruit			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Incisional hernia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus lesion			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			

subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heat stroke			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic pain			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	2 / 684 (0.29%)	1 / 804 (0.12%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 684 (0.00%)	2 / 804 (0.25%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 684 (0.15%)	1 / 804 (0.12%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 684 (0.15%)	1 / 804 (0.12%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Atrioventricular block complete			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nodal rhythm			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain injury			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Multiple system atrophy			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal nerve palsy			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post herpetic neuralgia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vocal cord paralysis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (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
Amyotrophic lateral sclerosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow oedema			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Cataract			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic polyp			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal symptom			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic gastroparesis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal necrosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal vascular malformation			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia, obstructive			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 necrosis			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemobilia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytoclastic vasculitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar pain			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute prerenal failure			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
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 bladder			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress urinary incontinence			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Carcinoid syndrome			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc degeneration			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	2 / 684 (0.29%)	0 / 804 (0.00%)	2 / 808 (0.25%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal abscess			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 684 (0.15%)	1 / 804 (0.12%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Sepsis			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon gangrene			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	1 / 684 (0.15%)	0 / 804 (0.00%)	1 / 808 (0.12%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	0 / 808 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Anacetrapib-2-year Extension Study	Placebo-2-year Extension Study	Anacetrapib-1-year Reversal Study
Total subjects affected by serious adverse events			
subjects affected / exposed	88 / 369 (23.85%)	90 / 433 (20.79%)	35 / 271 (12.92%)
number of deaths (all causes)	9	9	1
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign gastric neoplasm			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	2 / 271 (0.74%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoid tumour			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colon cancer			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip neoplasm malignant stage unspecified			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Malignant melanoma			
subjects affected / exposed	1 / 369 (0.27%)	3 / 433 (0.69%)	0 / 271 (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
Metastases to lung			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic neoplasm			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic renal cell carcinoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian neoplasm			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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	1 / 369 (0.27%)	2 / 433 (0.46%)	0 / 271 (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
Prostate cancer stage II			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma stage III			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	2 / 369 (0.54%)	1 / 433 (0.23%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	3 / 369 (0.81%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic lymphocytic leukaemia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	3 / 369 (0.81%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic squamous cell carcinoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Throat cancer			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular melanoma			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma metastatic			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (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
Metastases to bone			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (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
Ovarian adenoma			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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 cancer			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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 cell carcinoma			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectosigmoid cancer			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (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
Thyroid cancer			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyosarcoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
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-small cell lung cancer			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer stage IV			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioblastoma multiforme			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	2 / 369 (0.54%)	0 / 433 (0.00%)	0 / 271 (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
Aortic dissection			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial stenosis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery aneurysm			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral arterial occlusive disease			

subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery aneurysm			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Venous thrombosis limb			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral embolism			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Peripheral artery stenosis			

subjects affected / exposed	0 / 369 (0.00%)	2 / 433 (0.46%)	0 / 271 (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
Thrombophlebitis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
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	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	2 / 369 (0.54%)	0 / 433 (0.00%)	0 / 271 (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
Death			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	4 / 369 (1.08%)	9 / 433 (2.08%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sudden death			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Thrombosis in device			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrocution			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (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
Pyrexia			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod sting			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ovarian cyst			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatism			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine prolapse			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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	3 / 369 (0.81%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 obstructive pulmonary disease			
subjects affected / exposed	1 / 369 (0.27%)	2 / 433 (0.46%)	0 / 271 (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
Respiratory failure			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 chronic			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Suicide attempt			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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			
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid bruit			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus lesion			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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 fracture			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 / 369 (0.00%)	2 / 433 (0.46%)	0 / 271 (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
Head injury			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Heat stroke			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (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
Hip fracture			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle rupture			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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-traumatic pain			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hypertrophic cardiomyopathy			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
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 disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 369 (0.27%)	2 / 433 (0.46%)	0 / 271 (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
Acute myocardial infarction			
subjects affected / exposed	6 / 369 (1.63%)	3 / 433 (0.69%)	3 / 271 (1.11%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	6 / 369 (1.63%)	5 / 433 (1.15%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	1 / 369 (0.27%)	3 / 433 (0.69%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aortic valve disease			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	5 / 369 (1.36%)	1 / 433 (0.23%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
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 failure congestive			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	1 / 369 (0.27%)	2 / 433 (0.46%)	0 / 271 (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
Coronary artery occlusion			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			

subjects affected / exposed	2 / 369 (0.54%)	0 / 433 (0.00%)	0 / 271 (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
Myocardial infarction			
subjects affected / exposed	2 / 369 (0.54%)	2 / 433 (0.46%)	2 / 271 (0.74%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Palpitations			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular fibrillation			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (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
Bradycardia			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 369 (0.54%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (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
Nodal rhythm			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (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
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain injury			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriosclerosis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haematoma			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	2 / 369 (0.54%)	4 / 433 (0.92%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple system atrophy			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal nerve palsy			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post herpetic neuralgia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	2 / 369 (0.54%)	3 / 433 (0.69%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	2 / 369 (0.54%)	0 / 433 (0.00%)	0 / 271 (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
Vocal cord paralysis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal ganglia haemorrhage			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amyotrophic lateral sclerosis			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (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 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lacunar infarction			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
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 and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 369 (0.54%)	2 / 433 (0.46%)	0 / 271 (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
Thrombocytopenia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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 marrow oedema			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colonic polyp			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 369 (0.54%)	1 / 433 (0.23%)	0 / 271 (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
Gastrointestinal disorder			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal ischaemia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 369 (0.27%)	2 / 433 (0.46%)	0 / 271 (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
Enteritis			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal symptom			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 gastroparesis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Gastrointestinal necrosis			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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 vascular malformation			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 stenosis			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Umbilical hernia, obstructive			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
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, obstructive			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder necrosis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemobilia			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (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
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytoclastic vasculitis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar pain			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 ulcer			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute prerenal failure			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 369 (0.00%)	2 / 433 (0.46%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal artery stenosis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus bladder			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 failure			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
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			
Carcinoid syndrome			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intervertebral disc degeneration			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	2 / 369 (0.54%)	2 / 433 (0.46%)	2 / 271 (0.74%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 369 (0.27%)	1 / 433 (0.23%)	0 / 271 (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
Escherichia infection			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 369 (0.00%)	2 / 433 (0.46%)	0 / 271 (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
Groin abscess			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lobar pneumonia			
subjects affected / exposed	0 / 369 (0.00%)	3 / 433 (0.69%)	0 / 271 (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
Lung infection			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal abscess			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 369 (0.00%)	7 / 433 (1.62%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	2 / 369 (0.54%)	0 / 433 (0.00%)	0 / 271 (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
Sepsis			
subjects affected / exposed	1 / 369 (0.27%)	2 / 433 (0.46%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
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 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
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 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (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
Hyponatraemia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 369 (0.00%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 369 (0.00%)	1 / 433 (0.23%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			

subjects affected / exposed	2 / 369 (0.54%)	1 / 433 (0.23%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 369 (0.27%)	0 / 433 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo-1-year Reversal Study		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign gastric neoplasm			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder neoplasm			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Brain neoplasm				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carcinoid tumour				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal tract adenoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lip neoplasm malignant stage unspecified				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung neoplasm malignant				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant melanoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to lung				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic neoplasm				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic renal cell carcinoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian neoplasm				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic carcinoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer stage II				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma stage III				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Squamous cell carcinoma of skin				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid neoplasm				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic lymphocytic leukaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's lymphoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal cell carcinoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bowen's disease				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastatic squamous cell carcinoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Throat cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraocular melanoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung adenocarcinoma metastatic				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to bone				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to central nervous system				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to liver				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neoplasm malignant				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian adenoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cell carcinoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectosigmoid cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leiomyosarcoma				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-small cell lung cancer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate cancer stage IV				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glioblastoma multiforme				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Aortic aneurysm				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic dissection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arterial stenosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral artery aneurysm				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intermittent claudication				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intra-abdominal haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral arterial occlusive disease				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery aneurysm				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral ischaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis limb				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral embolism				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic aneurysm rupture				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral artery stenosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombophlebitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Chest discomfort				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden cardiac death				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden death				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombosis in device				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrocution				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Allergy to arthropod sting				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic shock				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Benign prostatic hyperplasia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostatism				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine prolapse				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asthma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Nasal septum deviation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oropharyngeal pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis chronic				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental status changes			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carotid bruit			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical vertebral fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incisional hernia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower limb fracture				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meniscus lesion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin laceration				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Craniocerebral injury				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Heat stroke				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple fractures				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle rupture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post-traumatic pain				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thermal burn				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulna fracture				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Hypertrophic cardiomyopathy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute coronary syndrome				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Acute myocardial infarction				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve disease				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriosclerosis coronary artery				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block second degree				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery occlusion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus bradycardia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular extrasystoles				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomyopathy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular fibrillation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bradycardia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular block complete				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure acute				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nodal rhythm				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Right ventricular failure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic cardiomyopathy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Brain injury				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral arteriosclerosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haematoma				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral infarction				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple system atrophy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Partial seizures				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peroneal nerve palsy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Petit mal epilepsy				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post herpetic neuralgia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient ischaemic attack				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vocal cord paralysis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Basal ganglia haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amyotrophic lateral sclerosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carpal tunnel syndrome				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lacunar infarction				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Convulsion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone marrow oedema			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abdominal pain upper				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal fissure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colonic polyp				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal haemorrhagic				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Food poisoning				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorder				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal ischaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesenteric vein thrombosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal perforation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper gastrointestinal haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal symptom				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic gastroparesis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspepsia				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal necrosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal vascular malformation				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal stenosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia, obstructive				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia, obstructive				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large intestine perforation				

subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder necrosis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemobilia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytoclastic vasculitis			

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scar pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin ulcer				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute prerenal failure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure acute				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal artery stenosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus bladder				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrotic syndrome				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress urinary incontinence				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Calculus ureteric				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Carcinoid syndrome				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperparathyroidism				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Arthralgia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Arthritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Costochondritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc degeneration				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar spinal stenosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal column stenosis				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal osteoarthritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal stiffness				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendonitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exostosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhabdomyolysis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic sinusitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic foot infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected skin ulcer				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lobar pneumonia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaria				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mastoiditis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasal abscess				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural infection				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vestibular neuronitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon gangrene				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal sepsis				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obesity				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				

subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Type 2 diabetes mellitus				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Placebo-Reversal Phase-Base Study	Placebo-Treatment Phase-Base Study	Anacetrapib 100 mg-Treatment Phase-Base Study
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 714 (0.00%)	600 / 804 (74.63%)	573 / 808 (70.92%)
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 714 (0.00%)	60 / 804 (7.46%)	47 / 808 (5.82%)
occurrences (all)	0	77	54
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 714 (0.00%)	33 / 804 (4.10%)	45 / 808 (5.57%)
occurrences (all)	0	36	48
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	0 / 714 (0.00%)	37 / 804 (4.60%)	46 / 808 (5.69%)
occurrences (all)	0	54	52
Back pain			
subjects affected / exposed	0 / 714 (0.00%)	36 / 804 (4.48%)	42 / 808 (5.20%)
occurrences (all)	0	40	46
Pain in extremity			
subjects affected / exposed	0 / 714 (0.00%)	23 / 804 (2.86%)	18 / 808 (2.23%)
occurrences (all)	0	23	20
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 714 (0.00%)	44 / 804 (5.47%)	36 / 808 (4.46%)
occurrences (all)	0	47	38
Nasopharyngitis			
subjects affected / exposed	0 / 714 (0.00%)	82 / 804 (10.20%)	87 / 808 (10.77%)
occurrences (all)	0	102	129
Upper respiratory tract infection			
subjects affected / exposed	0 / 714 (0.00%)	63 / 804 (7.84%)	47 / 808 (5.82%)
occurrences (all)	0	76	54
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 714 (0.00%)	25 / 804 (3.11%)	16 / 808 (1.98%)
occurrences (all)	0	27	16

Non-serious adverse events	Anacetrapid 100 mg-Reversal Phase-Base Study	Placebo-Post Treatment Phase-Base Study	Anacetrapib 100 mg-Post Treatment Phase-Base Study
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 684 (0.00%)	169 / 804 (21.02%)	158 / 808 (19.55%)
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 684 (0.00%)	3 / 804 (0.37%)	6 / 808 (0.74%)
occurrences (all)	0	3	6
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 684 (0.00%)	0 / 804 (0.00%)	5 / 808 (0.62%)
occurrences (all)	0	0	5
Musculoskeletal and connective tissue			

disorders			
Arthralgia			
subjects affected / exposed	0 / 684 (0.00%)	6 / 804 (0.75%)	4 / 808 (0.50%)
occurrences (all)	0	6	5
Back pain			
subjects affected / exposed	0 / 684 (0.00%)	8 / 804 (1.00%)	1 / 808 (0.12%)
occurrences (all)	0	8	1
Pain in extremity			
subjects affected / exposed	0 / 684 (0.00%)	2 / 804 (0.25%)	1 / 808 (0.12%)
occurrences (all)	0	2	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 684 (0.00%)	1 / 804 (0.12%)	3 / 808 (0.37%)
occurrences (all)	0	1	3
Nasopharyngitis			
subjects affected / exposed	0 / 684 (0.00%)	6 / 804 (0.75%)	12 / 808 (1.49%)
occurrences (all)	0	6	13
Upper respiratory tract infection			
subjects affected / exposed	0 / 684 (0.00%)	8 / 804 (1.00%)	6 / 808 (0.74%)
occurrences (all)	0	8	6
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 684 (0.00%)	4 / 804 (0.50%)	4 / 808 (0.50%)
occurrences (all)	0	4	4

Non-serious adverse events	Anacetrapib-2-year Extension Study	Placebo-2-year Extension Study	Anacetrapib-1-year Reversal Study
Total subjects affected by non-serious adverse events			
subjects affected / exposed	269 / 369 (72.90%)	313 / 433 (72.29%)	122 / 271 (45.02%)
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	13 / 369 (3.52%)	17 / 433 (3.93%)	3 / 271 (1.11%)
occurrences (all)	14	24	3
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	14 / 369 (3.79%)	19 / 433 (4.39%)	5 / 271 (1.85%)
occurrences (all)	14	21	5
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	16 / 369 (4.34%)	25 / 433 (5.77%)	3 / 271 (1.11%)
occurrences (all)	19	26	3
Back pain			
subjects affected / exposed	30 / 369 (8.13%)	28 / 433 (6.47%)	3 / 271 (1.11%)
occurrences (all)	36	29	3
Pain in extremity			
subjects affected / exposed	21 / 369 (5.69%)	16 / 433 (3.70%)	2 / 271 (0.74%)
occurrences (all)	26	19	2
Infections and infestations			
Bronchitis			
subjects affected / exposed	23 / 369 (6.23%)	11 / 433 (2.54%)	4 / 271 (1.48%)
occurrences (all)	25	13	4
Nasopharyngitis			
subjects affected / exposed	31 / 369 (8.40%)	34 / 433 (7.85%)	17 / 271 (6.27%)
occurrences (all)	39	39	20
Upper respiratory tract infection			
subjects affected / exposed	18 / 369 (4.88%)	32 / 433 (7.39%)	4 / 271 (1.48%)
occurrences (all)	28	43	4
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	8 / 369 (2.17%)	23 / 433 (5.31%)	2 / 271 (0.74%)
occurrences (all)	9	24	2

Non-serious adverse events	Placebo-1-year Reversal Study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

Arthralgia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Back pain subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Pain in extremity subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Metabolism and nutrition disorders Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 June 2008	AM1: Primary reason for the amendment was to revise the Participant Population to include only CHD/CHD risk-equivalent participants.
20 March 2009	AM2: Primary reason for the amendment was to add an interim safety analysis once all participants had reached Week 54.
19 August 2009	AM3: The primary reason for the amendment was to add the collection of safety follow-up information (serious cardiovascular adverse events or death) for discontinued participants at their intended Week 54 visit.
22 February 2010	AM4: The primary reason for this amendment was to extend the 12-week reversibility phase of Base Study by up to another 12 weeks (if required) in order to allow participants completing final visit (Week 88) to continue in the study until the planned extension study was ready for implementation at the site.
17 March 2010	Ext 10: The primary reason for this amendment was to add a 2-year Extension Study to the Base Study in order to further evaluate the long-term safety profile (~3.5years) and efficacy of anacetrapib in CHD/CHD-risk equivalent participants who were on ongoing therapy with a statin ± other lipid-modifying therapy.
07 March 2011	AM11 (AM1 to Ext10): The primary reason for this amendment was to add the results from the warfarin and digoxin drug interaction studies that was recently added to the Investigator's Brochure. As a result, digoxin or other cardiac glycosides and Coumadin (warfarin) or coumadin-like anticoagalants were no longer prohibited medications for the study. Added blood draws to estimate the time to steady state levels for anacetrapib. Also added an archive blood sample for biomarkers.
13 January 2012	AM12 (AM2 to Ext 10): The primary reason for this amendment was to extend the reversal period of the 2-year extension study from 12 weeks to 1-year.
24 April 2013	AM6: The primary reason for this amendment was to add a follow-up of 5 months up to 5 years for evaluation of pharmacokinetics and lipids for all participants who were previously treated with anacetrapib in the Base or Extension Studies (completed or discontinued). Additionally All women of child-bearing potential (WOCBP), who had previously received anacetrapib in the treatment phase would be contacted annually by the site for pregnancy and outcome. WOCBP would also receive guidance for proper use of contraception.
02 June 2013	AM14 (AM4 to Ext): The primary reason for this amendment was to reconcile the unblinding text such that participants can be unblinded after they complete the 2-year Extension Study on a rolling basis and then enrolled in AM6.
17 October 2013	AM7: The primary reason for the amendment was to add evaluations of participants to determine if anacetrapib levels were present in the adipose tissue, approximately 1 up to 5 years after the participant last took anacetrapib.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported