Clinical trial results:
A facilitated access program to provide Everolimus (RAD) for maintenance for patients completing therapy in RAD trials in solid organ transplantation

Summary

EudraCT number	2004-001473-25
Trial protocol	BE GB
Global end of trial date	14 February 2014

Results information

Result version number	v1 (current)
This version publication date	19 March 2020
First version publication date	19 March 2020

Trial information

Trial identification

Sponsor protocol code	CRAD001A2401

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00149981
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharmaceuticals AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharmaceuticals AG, 41 613241111,

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

• To facilitate the management of patients on maintenance immunosuppression therapy who are completing everolimus trials,
• To provide everolimus maintenance therapy through this access program and
• To collect and review safety data for up to 120 months or until the project has been discontinued whichever comes first.
• To collect and review safety data for up to 120 months or when Certican is commercially available in the given indication and reimbursed by appropriate payors or the project has been discontinued, whichever comes first.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 August 2003
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 13
Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Spain: 20
Country: Number of subjects enrolled	United States: 494
Country: Number of subjects enrolled	Australia: 34
Country: Number of subjects enrolled	Brazil: 98
Country: Number of subjects enrolled	Canada: 79
Country: Number of subjects enrolled	Czech Republic: 28
Country: Number of subjects enrolled	France: 61
Country: Number of subjects enrolled	Italy: 82
Country: Number of subjects enrolled	New Zealand: 12
Country: Number of subjects enrolled	Norway: 9
Country: Number of subjects enrolled	Poland: 4

Country: Number of subjects enrolled	Russian Federation: 5
Country: Number of subjects enrolled	South Africa: 8
Country: Number of subjects enrolled	Switzerland: 7
Country: Number of subjects enrolled	Taiwan: 47
Worldwide total number of subjects	1024
EEA total number of subjects	240

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)	9
Adolescents (12-17 years)	9
Adults (18-64 years)	908
From 65 to 84 years	98
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Approximately 1000 adult (kidney, pancreas, heart, liver, or lung) and pediatric transplant patients at around 500 sites who were previously enrolled and were in the follow-up phases in Novartis transplant trials were planned for enrollment in this study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Renal - Adult Patients

Arm description: -

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

Dosage and administration details:

Everolimus was provided in blister packs as 0.25 mg, 0.5 mg and 0.75 mg tablets. For pediatric patients who do not swallow tablets, a fast-dispersible tablet formulation of 0.25 mg nd 0.1 mg was provided.

Arm title	Pancreas- Kidney - Adult Patients

Arm description: -

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

Dosage and administration details:

Everolimus was provided in blister packs as 0.25 mg, 0.5 mg and 0.75 mg tablets. For pediatric patients who do not swallow tablets, a fast-dispersible tablet formulation of 0.25 mg nd 0.1 mg was provided.

Arm title	Liver - Adult Patients

Arm description: -

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

Dosage and administration details:

Everolimus was provided in blister packs as 0.25 mg, 0.5 mg and 0.75 mg tablets. For pediatric patients who do not swallow tablets, a fast-dispersible tablet formulation of 0.25 mg nd 0.1 mg was provided.

Arm title	Heart - Adult Patients
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Everolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Everolimus was provided in blister packs as 0.25 mg, 0.5 mg and 0.75 mg tablets. For pediatric patients who do not swallow tablets, a fast-dispersible tablet formulation of 0.25 mg nd 0.1 mg was provided.

Arm title	Lung/ Heart- Lung - Adult Patients
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Everolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Everolimus was provided in blister packs as 0.25 mg, 0.5 mg and 0.75 mg tablets. For pediatric patients who do not swallow tablets, a fast-dispersible tablet formulation of 0.25 mg nd 0.1 mg was provided.

Arm title	Renal - Pediatric
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Everolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Everolimus was provided in blister packs as 0.25 mg, 0.5 mg and 0.75 mg tablets. For pediatric patients who do not swallow tablets, a fast-dispersible tablet formulation of 0.25 mg nd 0.1 mg was provided.

Number of subjects in period 1	Renal - Adult Patients	Pancreas- Kidney - Adult Patients	Liver - Adult Patients
Started	701	8	18
Completed	482	4	8
Not completed	219	4	10
Patient Withdrew Consent	17	-	-
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	98	3	4
Death	24	-	1
Abnormal Laboratory Value(s)	8	1	-
Unsatisfactory Therapeutic Effect	10	-	-
Administrative Problems	16	-	-

Protocol Violation	1	-	-
Abnormal Test Procedure Result(s)	1	-	-
Patient's Condition No Longer Requires Study Drug	5	-	1
Lost to follow-up	12	-	2
Missing	27	-	2

Number of subjects in period 1	Heart - Adult Patients	Lung/ Heart- Lung - Adult Patients	Renal - Pediatric
Started	254	24	19
Completed	167	12	5
Not completed	87	12	14
Patient Withdrew Consent	-	-	-
Consent withdrawn by subject	7	-	-
Adverse event, non-fatal	31	3	2
Death	20	3	-
Abnormal Laboratory Value(s)	2	-	-
Unsatisfactory Therapeutic Effect	-	-	1
Administrative Problems	11	2	10
Protocol Violation	4	-	-
Abnormal Test Procedure Result(s)	2	-	1
Patient's Condition No Longer Requires Study Drug	1	1	-
Lost to follow-up	6	-	-
Missing	3	3	-

Baseline characteristics

Reporting groups	
Reporting group title	Renal - Adult Patients
Reporting group description: -	
Reporting group title	Pancreas- Kidney - Adult Patients
Reporting group description: -	
Reporting group title	Liver - Adult Patients
Reporting group description: -	
Reporting group title	Heart - Adult Patients
Reporting group description: -	
Reporting group title	Lung/ Heart- Lung - Adult Patients
Reporting group description: -	
Reporting group title	Renal - Pediatric
Reporting group description: -	

Reporting group values	Renal - Adult Patients	Pancreas- Kidney - Adult Patients	Liver - Adult Patients
Number of subjects	701	8	18
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	651	8	18
From 65-84 years	50	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	48.0	40.5	47.1
standard deviation	± 11.69	± 4.57	± 11.71
Gender categorical Units: Subjects			
Female	227	4	10
Male	474	4	8

Reporting group values	Heart - Adult Patients	Lung/ Heart- Lung - Adult Patients	Renal - Pediatric
Number of subjects	254	24	19
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	9
Adolescents (12-17 years)	0	0	9
Adults (18-64 years)	208	22	1
From 65-84 years	46	2	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	53.3	50.1	11.2
standard deviation	± 11.61	± 12.35	± 4.67
Gender categorical			
Units: Subjects			
Female	53	8	6
Male	201	16	13

Reporting group values	Total		
Number of subjects	1024		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	9		
Adolescents (12-17 years)	9		
Adults (18-64 years)	908		
From 65-84 years	98		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	308		
Male	716		

End points

End points reporting groups

Reporting group title	Renal - Adult Patients
Reporting group description: -	
Reporting group title	Pancreas- Kidney - Adult Patients
Reporting group description: -	
Reporting group title	Liver - Adult Patients
Reporting group description: -	
Reporting group title	Heart - Adult Patients
Reporting group description: -	
Reporting group title	Lung/ Heart- Lung - Adult Patients
Reporting group description: -	
Reporting group title	Renal - Pediatric
Reporting group description: -	
Subject analysis set title	Pediatric Renal - male
Subject analysis set type	Sub-group analysis
Subject analysis set description: Pediatric renal, male subjects.	
Subject analysis set title	Pediatric Renal - female
Subject analysis set type	Sub-group analysis
Subject analysis set description: Pediatric renal, female subjects.	

Primary: Number of Participants with Adverse Events

End point title	Number of Participants with Adverse Events[1]

End point description:

An adverse event is any untoward medical event that occurs in a participant administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product.

End point type	Primary

End point timeframe:

124 months

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 analyses have been planned for this primary end point.

End point values	Renal - Adult Patients	Pancreas- Kidney - Adult Patients	Liver - Adult Patients	Heart - Adult Patients
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	701[2]	8[3]	18[4]	254[5]
Units: participants				
number (not applicable)				
Any Notable Event	297	8	10	123
Deaths	24	0	1	20
Any Serious Adverse Events (SAE)	256	8	9	112
Non-Fatal SAE	233	8	8	92
Permanent Discontinuation of Study Drug	104	3	3	37
Adverse Drop Out	107	4	4	35

Notes:

[2] - Enrolled Analysis Set

[3] - Enrolled Analysis Set

[4] - Enrolled Analysis Set

[5] - Enrolled Analysis Set

End point values	Lung/ Heart-Lung - Adult Patients	Renal - Pediatric		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24[6]	19[7]		
Units: participants				
number (not applicable)				
Any Notable Event	12	8		
Deaths	3	0		
Any Serious Adverse Events (SAE)	11	7		
Non-Fatal SAE	9	7		
Permanent Discontinuation of Study Drug	4	3		
Adverse Drop Out	3	3		

Notes:

[6] - Enrolled Analysis Set

[7] - Enrolled Analysis Set

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of patients in each Tanner stage, by indication and visit

End point title	Percentage of patients in each Tanner stage, by indication and visit[8]

End point description:

Tanner scale defined as a scale used to measure visible changes during puberty commonly referred to as "Tanner stages". Female participants will be evaluated for breast development and pubic hair distribution and male participants are evaluated for development of external genitalia and pubic hair distribution, based on a 5-stage ordinal scale ranging from TS 1 (prepubertal/preadolescent characteristics) to TS 5 (mature or adult characteristics).
Tanner stage was summarized using frequency distributions at each visit for pediatric patients only.

End point type	Primary

End point timeframe:

Baseline up to 60 months.

Notes:

[8] - 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 analyses have been planned for this primary end point.

End point values	Pediatric Renal - male	Pediatric Renal - female		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	6		
Units: percentage of patients (%)				
number (not applicable)				
Baseline - Stage 1	40.0	0.0		
Baseline - Stage 2	10.0	50.0		
Baseline - Stage 3	10.0	0.0		

Baseline - Stage 4	10.0	0.0		
Baseline - Stage 5	20.0	25.0		
Baseline - Missing	10.0	25.0		
Month 12 - Stage 1	10.0	0.0		
Month 12 - Stage 2	0.0	0.0		
Month 12 - Stage 3	0.0	0.0		
Month 12 - Stage 4	0.0	0.0		
Month 12 - Stage 5	20.0	0.0		
Month 12 - Missing	70.0	100.0		
Month 24 - Stage 1	33.3	0.0		
Month 24 - Stage 2	0.0	0.0		
Month 24 - Stage 3	0.0	0.0		
Month 24 - Stage 4	0.0	0.0		
Month 24 - Stage 5	66.7	0.0		
Month 24 - Missing	0.0	0.0		
Month 60 - Stage 1	0.0	0.0		
Month 60 - Stage 2	0.0	0.0		
Month 60 - Stage 3	0.0	0.0		
Month 60 - Stage 4	50.0	0.0		
Month 60 - Stage 5	50.0	0.0		
Month 60 - Missing	0.0	0.0		

Statistical analyses

No statistical analyses for this end point

Primary: Summary statistics of Estimated glomerular filtration rate (eGFR) by indication and visit

End point title	Summary statistics of Estimated glomerular filtration rate (eGFR) by indication and visit[9][10]

End point description:

The main renal function endpoint is calculated GFR using the MDRD formula (adult patients).
The Modification of Diet in Renal Disease (MDRD) Study equation equation is the most widely used IDMS traceable equations for estimating GFR in patients age 18 and over.

End point type	Primary

End point timeframe:

up to 124 months

Notes:

[9] - 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 analyses have been planned for this primary end point.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was only reported for this subset of patients for this outcome measure.

End point values	Renal - Adult Patients	Pancreas-Kidney - Adult Patients	Liver - Adult Patients	Heart - Adult Patients
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	701[11]	8[12]	18[13]	254[14]
Units: mL/min/1.73m^2				
arithmetic mean (standard deviation)				
Month 6 (Year 0)	51.43 (± 18.969)	36.23 (± 0)	0 (± 0)	54.53 (± 21.203)
Month 12 (Year 1)	51.43 (± 20.301)	43.45 (± 18.349)	75.43 (± 45.270)	55.28 (± 42.954)
Month 24 (Year 2)	51.14 (± 33.919)	52.58 (± 23.352)	57.31 (± 19.919)	56.19 (± 69.863)
Month 36 (Year 3)	49.67 (± 18.180)	51.48 (± 21.634)	60.39 (± 23.710)	59.38 (± 90.280)
Month 48 (Year 4)	48.85 (± 18.412)	53.68 (± 6.908)	55.99 (± 18.646)	60.04 (± 102.532)
Month 60 (Year 5)	49.80 (± 19.092)	49.33 (± 5.155)	55.49 (± 16.432)	41.61 (± 16.133)
Month 72 (Year 6)	46.00 (± 16.220)	66.22 (± 30.943)	55.37 (± 20.179)	37.82 (± 14.802)
Month 84 (Year 7)	32.07 (± 12.596)	0 (± 0)	50.90 (± 26.778)	37.91 (± 17.560)
Month 96 (Year 8)	30.62 (± 16.958)	0 (± 0)	57.25 (± 1.266)	36.81 (± 22.041)
Month 108 (Year 9)	0 (± 0)	0 (± 0)	77.67 (± 8.584)	34.96 (± 0)
Study Endpoint Visit (SEP) Visit	48.21 (± 20.100)	45.15 (± 22.700)	56.19 (± 20.912)	52.02 (± 64.853)
Treatment Endpoint Visit (TEP) Visit	48.59 (± 19.684)	45.15 (± 22.700)	59.26 (± 20.786)	53.28 (± 69.404)

Notes:

[11] - n = 200, 388, 300, 189, 134, 107, 59, 6, 3, 0, 499, 434; Enrolled Set

[12] - n = 1, 6, 4, 4, 2, 2, 2, 0, 0, 0, 6, 6; Enrolled Set

[13] - n = 0, 11, 13, 7, 7, 7, 6, 4, 2, 2, 14, 12; Enrolled Set

[14] - n = 77, 162, 142, 117, 73, 43, 33, 31, 7, 1, 202, 171; Enrolled Set

End point values	Lung/ Heart-Lung - Adult Patients			
Subject group type	Reporting group			
Number of subjects analysed	24[15]			
Units: mL/min/1.73m^2				
arithmetic mean (standard deviation)				
Month 6 (Year 0)	50.21 (± 8.794)			
Month 12 (Year 1)	45.05 (± 17.321)			
Month 24 (Year 2)	43.63 (± 14.455)			
Month 36 (Year 3)	47.56 (± 16.204)			
Month 48 (Year 4)	44.95 (± 24.190)			
Month 60 (Year 5)	54.15 (± 0)			
Month 72 (Year 6)	43.70 (± 14.786)			
Month 84 (Year 7)	35.51 (± 0)			

Month 96 (Year 8)	47.71 (± 15.945)			
Month 108 (Year 9)	0 (± 0)			
Study Endpoint Visit (SEP) Visit	45.98 (± 15.199)			
Treatment Endpoint Visit (TEP) Visit	48.24 (± 15.095)			

Notes:

[15] - n = 5, 11, 4, 3, 3, 1, 2, 1, 2, 0, 15, 13

Enrolled Set

Statistical analyses

No statistical analyses for this end point

Primary: Summary statistics of Estimated glomerular filtration rate (eGFR) by indication and visit- Pediatric

End point title	Summary statistics of Estimated glomerular filtration rate (eGFR) by indication and visit- Pediatric[16][17]

End point description:

The main renal function endpoint is calculated GFR using the Schwarz formula for pediatric patients.

End point type	Primary

End point timeframe:

up to 124 months

Notes:

[16] - 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 analyses have been planned for this primary end point.

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Data was only reported for this subset of patients for this outcome measure.

End point values	Renal - Pediatric			
Subject group type	Reporting group			
Number of subjects analysed	19[18]			
Units: mL/min/SA				
arithmetic mean (standard deviation)				
Month 6 (Year 0)	0 (± 0)			
Month 12 (Year 1)	48.31 (± 17.154)			
Month 24 (Year 2)	54.37 (± 15.845)			
Month 36 (Year 3)	49.60 (± 32.446)			
Month 48 (Year 4)	56.70 (± 22.535)			
Month 60 (Year 5)	76.88 (± 0)			
Month 72 (Year 6)	0 (± 0)			
Month 84 (Year 7)	0 (± 0)			
Month 96 (Year 8)	0 (± 0)			
Month 108 (Year 9)	0 (± 0)			
SEP Visit	46.29 (± 28.399)			

TEP Visit	46.29 (± 28.399)			

Notes:

[18] - n = 0, 3, 3, 3, 2, 1, 0, 0, 0, 0, 3, 3; Enrolled Set

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Renal
Reporting group description:	
Renal	
Reporting group title	Pancreas-Kidney
Reporting group description:	
Pancreas-Kidney	
Reporting group title	Liver
Reporting group description:	
Liver	
Reporting group title	Heart
Reporting group description:	
Heart	
Reporting group title	Lung/Heart-Lung
Reporting group description:	
Lung/Heart-Lung	
Reporting group title	Pediatric Renal
Reporting group description:	
Pediatric Renal	

Serious adverse events	Renal	Pancreas-Kidney	Liver
Total subjects affected by serious adverse events			
subjects affected / exposed	256 / 701 (36.52%)	8 / 8 (100.00%)	9 / 18 (50.00%)
number of deaths (all causes)	24	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	7 / 701 (1.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BENIGN LUNG NEOPLASM			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
CERVIX NEOPLASM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 ADENOMA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER METASTATIC			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPSTEIN-BARR VIRUS ASSOCIATED LYMPHOPROLIFERATIVE DISORDER			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 AND NECK CANCER			

subjects affected / exposed	4 / 701 (0.57%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC NEOPLASM MALIGNANT			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INVASIVE DUCTAL BREAST CARCINOMA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 SQUAMOUS CELL CARCINOMA STAGE UNSPECIFIED			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 GASTRIC CANCER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC RENAL CELL CARCINOMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYELOPROLIFERATIVE DISORDER			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 CAVITY CANCER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 TRANSPLANT LYMPHOPROLIFERATIVE DISORDER			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
RENAL CANCER			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 NEOPLASM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN CANCER			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL CELL LUNG CANCER STAGE UNSPECIFIED			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SOFT TISSUE NEOPLASM			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
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	3 / 701 (0.43%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF HEAD AND NECK			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	7 / 701 (1.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
AORTIC ANEURYSM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL HAEMORRHAGE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CIRCULATORY COLLAPSE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	13 / 701 (1.85%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC VASCULAR DISORDER			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (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
FEMORAL ARTERIAL STENOSIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	4 / 701 (0.57%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSIVE CRISIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIC SHOCK			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERMITTENT CLAUDICATION			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCELE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT HYPERTENSION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL ISCHAEMIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 VASCULAR DISORDER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK			

subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOPHLEBITIS			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
THROMBOSIS			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
VENOUS OCCLUSION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
CORONARY ANGIOPLASTY			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEART TRANSPLANT			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATECTOMY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ADVERSE DRUG REACTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ASTHENIA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
CHEST DISCOMFORT			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (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
DEVICE MALFUNCTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 OCCLUSION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
HERNIA OBSTRUCTIVE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHERMIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMPAIRED HEALING			

subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
MULTI-ORGAN FAILURE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
OEDEMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	4 / 701 (0.57%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	16 / 701 (2.28%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN CARDIAC DEATH			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ALLERGIC OEDEMA			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAPHYLACTIC REACTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DRUG HYPERSENSITIVITY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEART TRANSPLANT REJECTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KIDNEY TRANSPLANT REJECTION			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSPLANT REJECTION			
subjects affected / exposed	7 / 701 (1.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
ABORTED PREGNANCY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PREGNANCY OF PARTNER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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			

ENDOMETRIOSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVARIAN CYST			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATOMEGALY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ALVEOLITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIAL HYPERREACTIVITY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BRONCHOSPASM			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIAPHRAGMATIC HERNIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	7 / 701 (1.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EMPHYSEMA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			

subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
LUNG DISORDER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	6 / 701 (0.86%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURITIC PAIN			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
PNEUMOTHORAX			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRODUCTIVE COUGH			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 ALVEOLAR HAEMORRHAGE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY FIBROSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 HYPERTENSION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY MASS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 OEDEMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 DISTRESS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 FAILURE			

subjects affected / exposed	1 / 701 (0.14%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
SLEEP APNOEA SYNDROME			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DELIRIUM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MAJOR DEPRESSION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	1 / 8 (12.50%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BLEEDING TIME PROLONGED			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD CREATININE INCREASED			

subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATHETERISATION CARDIAC			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT INCREASED			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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			
ANIMAL SCRATCH			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANKLE FRACTURE			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURNS SECOND DEGREE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEMICAL POISONING			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 ALLOGRAFT NEPHROPATHY			
subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATIONS OF TRANSPLANTED KIDNEY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATIONS OF TRANSPLANTED PANCREAS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMORAL NECK FRACTURE			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	2 / 701 (0.29%)	1 / 8 (12.50%)	0 / 18 (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 STOMA COMPLICATION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (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
GRAFT LOSS			
subjects affected / exposed	7 / 701 (1.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	3 / 701 (0.43%)	1 / 8 (12.50%)	0 / 18 (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
INCISIONAL HERNIA			
subjects affected / exposed	7 / 701 (1.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISIONAL HERNIA, OBSTRUCTIVE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACERATION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER LIMB FRACTURE			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INJURY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHARYNGEAL INJURY			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMATOMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIB FRACTURE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON RUPTURE			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	2 / 701 (0.29%)	1 / 8 (12.50%)	0 / 18 (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
TRANSPLANT DYSFUNCTION			
subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSPLANT FAILURE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC HAEMATOMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE CORONARY SYNDROME			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	8 / 701 (1.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
ANGINA PECTORIS			
subjects affected / exposed	6 / 701 (0.86%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARRHYTHMIA			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.71%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FLUTTER			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL THROMBOSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE ACUTE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
CARDIAC FAILURE CHRONIC			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	10 / 701 (1.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
CARDIOGENIC SHOCK			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
CORONARY ARTERY DISEASE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
CORONARY ARTERY INSUFFICIENCY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (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
CORONARY ARTERY OCCLUSION			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	5 / 701 (0.71%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
PALPITATIONS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULSELESS ELECTRICAL ACTIVITY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SICK SINUS SYNDROME			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINOATRIAL BLOCK			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 CARDIOMYOPATHY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRICUSPID VALVE INCOMPETENCE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL DISORDER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL HAEMORRHAGE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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 INFARCTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL ISCHAEMIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	7 / 701 (1.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (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
FEBRILE CONVULSION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGIC STROKE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEMIPARESIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRACRANIAL ANEURYSM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC CEREBRAL INFARCTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUMBAR RADICULOPATHY			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCLONUS			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRESYNCOPE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
SYNCOPE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA OF CHRONIC DISEASE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOLYTIC ANAEMIA			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHADENITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MICROCYTIC ANAEMIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCYTOPENIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPLENIC VEIN THROMBOSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPONTANEOUS HAEMATOMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THROMBOCYTOPENIA			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 disorders			
ABDOMINAL ADHESIONS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL HERNIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL HERNIA OBSTRUCTIVE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 MASS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONSTIPATION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC GASTROPARESIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIAPHRAGMATIC HERNIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	9 / 701 (1.28%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIEULAFOY'S VASCULAR MALFORMATION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPEPSIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOD POISONING			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC ULCER			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 EROSIVE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 HAEMORRHAGE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 NECROSIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEUS			
subjects affected / exposed	1 / 701 (0.14%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGUINAL HERNIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 OBSTRUCTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 INTESTINAL OBSTRUCTION			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	11 / 701 (1.57%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL ULCER			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 DUCT DILATATION			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
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			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 ACUTE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOPERITONEUM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMORRHAGE			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UPPER GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	9 / 701 (1.28%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STONE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
BILIARY COLIC			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGIOLITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS			

subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
CHOLELITHIASIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 DISORDER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC CYST			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FIBROSIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FUNCTION ABNORMAL			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 HEPATITIS			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER DISORDER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
ANGIOEDEMA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
DIABETIC ULCER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYTHEMA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYTHEMA NODOSUM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERHIDROSIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN LESION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN ULCER			

subjects affected / exposed	2 / 701 (0.29%)	1 / 8 (12.50%)	0 / 18 (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
Renal and urinary disorders			
ACUTE PRERENAL FAILURE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AZOTAEMIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOCAL SEGMENTAL GLOMERULOSCLEROSIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IGA NEPHROPATHY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHROPATHY TOXIC			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE UROPATHY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROTEINURIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELOCALIECTASIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 ARTERY STENOSIS			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL COLIC			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE ACUTE			
subjects affected / exposed	21 / 701 (3.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 23	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE CHRONIC			

subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL IMPAIRMENT			
subjects affected / exposed	6 / 701 (0.86%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL INSUFFICIENCY			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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			
HYPERPARATHYROIDISM			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACK PAIN			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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

BURSITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GOUTY ARTHRITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONARTHRITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROPATHIC ARTHROPATHY			

subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOARTHRITIS			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEONECROSIS			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIOSTITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHABDOMYOLYSIS			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
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 PAIN			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDONITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABDOMINAL ABSCESS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS LIMB			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS PERFORATED			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIOVENOUS GRAFT SITE INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	3 / 701 (0.43%)	1 / 8 (12.50%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL PYELONEPHRITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL SEPSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BK VIRUS INFECTION			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHITIS			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOPNEUMONIA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
BRONCHOPULMONARY ASPERGILLOSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CANDIDA INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATHETER SITE CELLULITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CELLULITIS			
subjects affected / exposed	8 / 701 (1.14%)	1 / 8 (12.50%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 11	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC SINUSITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			

subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE SEPSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOMEGALOVIRUS OESOPHAGITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIVERTICULITIS			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
EPSTEIN-BARR VIRUS INFECTION			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 BACTERAEMIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	10 / 701 (1.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS VIRAL			
subjects affected / exposed	4 / 701 (0.57%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATITIS B			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HUMAN EHRLICHIOSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISION SITE CELLULITIS			

subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED LYMPHOCELE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JC VIRUS INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JOINT ABSCESS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	1 / 8 (12.50%)	0 / 18 (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
LIVER ABSCESS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOBAR PNEUMONIA			

subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENINGITIS PNEUMOCOCCAL			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NOSOCOMIAL INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOMYELITIS			

subjects affected / exposed	2 / 701 (0.29%)	1 / 8 (12.50%)	0 / 18 (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
OTITIS MEDIA BACTERIAL			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIRECTAL ABSCESS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	31 / 701 (4.42%)	1 / 8 (12.50%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 34	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
PNEUMONIA BORDETELLA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 KLEBSIELLA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 LEGIONELLA			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 PRIMARY ATYPICAL			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA PSEUDOMONAL			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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 STREPTOCOCCAL			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA VIRAL			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	8 / 701 (1.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS ACUTE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (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
SEPSIS			
subjects affected / exposed	7 / 701 (1.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	4 / 701 (0.57%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
SKIN INFECTION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL SEPSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
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	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	20 / 701 (2.85%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 24	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	7 / 701 (1.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIRAL DIARRHOEA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIRAL INFECTION			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WOUND INFECTION STAPHYLOCOCCAL			

subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
DEHYDRATION			
subjects affected / exposed	9 / 701 (1.28%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETES MELLITUS			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
DIABETIC FOOT			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC KETOACIDOSIS			
subjects affected / exposed	4 / 701 (0.57%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLUID OVERLOAD			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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
GOUT			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERGLYCAEMIA			

subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERKALAEMIA			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERLIPIDAEMIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOGLYCAEMIA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (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

Serious adverse events	Heart	Lung/Heart-Lung	Pediatric Renal
Total subjects affected by serious adverse events			
subjects affected / exposed	112 / 254 (44.09%)	11 / 24 (45.83%)	7 / 19 (36.84%)
number of deaths (all causes)	20	3	0
number of deaths resulting from adverse events	0	0	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	4 / 254 (1.57%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BENIGN LUNG NEOPLASM			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER CANCER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BOWEN'S DISEASE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BREAST CANCER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVIX NEOPLASM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLON ADENOMA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOMETRIAL CANCER METASTATIC			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

EPSTEIN-BARR VIRUS ASSOCIATED LYMPHOPROLIFERATIVE DISORDER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEAD AND NECK CANCER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC NEOPLASM MALIGNANT			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
INVASIVE DUCTAL BREAST CARCINOMA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
LUNG SQUAMOUS CELL CARCINOMA STAGE UNSPECIFIED			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
METASTATIC GASTRIC CANCER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYELOPROLIFERATIVE DISORDER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASAL CAVITY CANCER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 TRANSPLANT LYMPHOPROLIFERATIVE DISORDER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 CANCER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 NEOPLASM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 CANCER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL CELL LUNG CANCER STAGE			

UNSPECIFIED			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
SOFT TISSUE NEOPLASM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	5 / 254 (1.97%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF HEAD AND NECK			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
AORTIC ANEURYSM			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIAL HAEMORRHAGE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CIRCULATORY COLLAPSE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETIC VASCULAR DISORDER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 ARTERIAL STENOSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATOMA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSIVE CRISIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOTENSION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIC SHOCK			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOCELE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOEDEMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 HYPERTENSION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORTHOSTATIC HYPOTENSION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL ARTERIAL OCCLUSIVE DISEASE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL VASCULAR DISORDER			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHOCK			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 OCCLUSION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
Surgical and medical procedures			
CORONARY ANGIOPLASTY			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEART TRANSPLANT			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATECTOMY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			

ADVERSE DRUG REACTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASTHENIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST DISCOMFORT			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEATH			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
DEVICE MALFUNCTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE OCCLUSION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERNIA OBSTRUCTIVE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTHERMIA			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IMPAIRED HEALING			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALAISE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTI-ORGAN FAILURE			
subjects affected / exposed	2 / 254 (0.79%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OEDEMA PERIPHERAL			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
PYREXIA			
subjects affected / exposed	4 / 254 (1.57%)	1 / 24 (4.17%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUDDEN CARDIAC DEATH			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
ALLERGIC OEDEMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 REACTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEART TRANSPLANT REJECTION			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
KIDNEY TRANSPLANT REJECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSPLANT REJECTION			
subjects affected / exposed	6 / 254 (2.36%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
ABORTED PREGNANCY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PREGNANCY OF PARTNER			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
ENDOMETRIOSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATOMEGALY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
ACUTE RESPIRATORY DISTRESS SYNDROME			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ALVEOLITIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATELECTASIS			

subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIAL HYPERREACTIVITY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOSPASM			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC OBSTRUCTIVE PULMONARY DISEASE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
COUGH			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIAPHRAGMATIC HERNIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA			
subjects affected / exposed	4 / 254 (1.57%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPNOEA EXERTIONAL			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EMPHYSEMA			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPISTAXIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOXIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERSTITIAL LUNG DISEASE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 DISORDER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURAL EFFUSION			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PLEURITIC PAIN			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOTHORAX			
subjects affected / exposed	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRODUCTIVE COUGH			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY ALVEOLAR HAEMORRHAGE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
PULMONARY FIBROSIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY HYPERTENSION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 MASS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY OEDEMA			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 FAILURE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
SLEEP APNOEA SYNDROME			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CONFUSIONAL STATE			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
DELIRIUM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MAJOR DEPRESSION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENTAL STATUS CHANGES			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
BLEEDING TIME PROLONGED			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 CREATININE INCREASED			
subjects affected / exposed	3 / 254 (1.18%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATHETERISATION CARDIAC			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EJECTION FRACTION DECREASED			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT INCREASED			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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, poisoning and procedural complications			
ANIMAL SCRATCH			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANKLE FRACTURE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURNS SECOND DEGREE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL VERTEBRAL FRACTURE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEMICAL POISONING			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 ALLOGRAFT NEPHROPATHY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COMPLICATIONS OF TRANSPLANTED KIDNEY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COMPLICATIONS OF TRANSPLANTED PANCREAS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 NECK FRACTURE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 STOMA COMPLICATION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GRAFT LOSS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISIONAL HERNIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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, OBSTRUCTIVE			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LACERATION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 INJURY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OVERDOSE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PHARYNGEAL INJURY			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMATOMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOXICITY TO VARIOUS AGENTS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSPLANT DYSFUNCTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSPLANT FAILURE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC HAEMATOMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARRHYTHMIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FLUTTER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL THROMBOSIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK COMPLETE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC ARREST			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE ACUTE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 CHRONIC			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
CARDIOGENIC SHOCK			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 DISEASE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY INSUFFICIENCY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERICARDIAL EFFUSION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULSELESS ELECTRICAL ACTIVITY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SICK SINUS SYNDROME			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINOATRIAL BLOCK			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 CARDIOMYOPATHY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRICUSPID VALVE INCOMPETENCE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL DISORDER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 ISCHAEMIA			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE CONVULSION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMORRHAGIC STROKE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHE			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
HEMIPARESIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTRACRANIAL ANEURYSM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC CEREBRAL INFARCTION			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUMBAR RADICULOPATHY			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCLONUS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	7 / 254 (2.76%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA OF CHRONIC DISEASE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOLYTIC ANAEMIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHADENITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MICROCYTIC ANAEMIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCYTOPENIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPLENIC VEIN THROMBOSIS			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPONTANEOUS HAEMATOMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 disorders			
ABDOMINAL ADHESIONS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 DISTENSION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL HERNIA			
subjects affected / exposed	5 / 254 (1.97%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL HERNIA OBSTRUCTIVE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL MASS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			

subjects affected / exposed	4 / 254 (1.57%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASCITES			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIAPHRAGMATIC HERNIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIEULAFOY'S VASCULAR MALFORMATION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRIC ULCER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS EROSIVE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEUS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGUINAL HERNIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
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 INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OESOPHAGEAL ULCER			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATIC DUCT DILATATION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
PANCREATITIS ACUTE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PEPTIC ULCER			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOPERITONEUM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RETROPERITONEAL HAEMORRHAGE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
VOMITING			
subjects affected / exposed	5 / 254 (1.97%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STONE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BILIARY COLIC			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGIOLITIS			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 ACUTE			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLELITHIASIS			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
GALLBLADDER DISORDER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC CYST			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FIBROSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FUNCTION ABNORMAL			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ISCHAEMIC HEPATITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JAUNDICE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER DISORDER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 ULCER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYTHEMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ERYTHEMA NODOSUM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERHIDROSIS			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 LESION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AZOTAEMIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOCAL SEGMENTAL GLOMERULOSCLEROSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IGA NEPHROPATHY			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (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
NEPHROPATHY TOXIC			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSTRUCTIVE UROPATHY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROTEINURIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELOCALIECTASIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 COLIC			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			

subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
RENAL FAILURE ACUTE			
subjects affected / exposed	7 / 254 (2.76%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE CHRONIC			
subjects affected / exposed	5 / 254 (1.97%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
RENAL IMPAIRMENT			
subjects affected / exposed	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL INSUFFICIENCY			
subjects affected / exposed	6 / 254 (2.36%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETERIC OBSTRUCTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
HYPERPARATHYROIDISM			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ARTHRITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURSITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GOUTY ARTHRITIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MONARTHRITIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULAR WEAKNESS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MUSCULOSKELETAL PAIN			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROPATHIC ARTHROPATHY			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
OSTEONECROSIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (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
PERIOSTITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	3 / 254 (1.18%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL PAIN			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
ABDOMINAL ABSCESS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS LIMB			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS PERFORATED			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTERIOVENOUS GRAFT SITE INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERAEMIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL PYELONEPHRITIS			

subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BACTERIAL SEPSIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BK VIRUS INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHOPULMONARY ASPERGILLOSIS			
subjects affected / exposed	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (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
CANDIDA INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATHETER SITE CELLULITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	5 / 254 (1.97%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC SINUSITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE COLITIS			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
CLOSTRIDIUM DIFFICILE INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CLOSTRIDIUM DIFFICILE SEPSIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOMEGALOVIRUS INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CYTOMEGALOVIRUS OESOPHAGITIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEVICE RELATED INFECTION			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
EPSTEIN-BARR VIRUS INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ESCHERICHIA BACTERAEMIA			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEBRILE INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS VIRAL			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 B			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HERPES ZOSTER			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HUMAN EHRLICHIOSIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INCISION SITE CELLULITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 LYMPHOCELE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFLUENZA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
JC VIRUS INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 ABSCESS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
KLEBSIELLA INFECTION			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER ABSCESS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOCALISED INFECTION			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (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
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENINGITIS PNEUMOCOCCAL			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NOSOCOMIAL INFECTION			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOMYELITIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OTITIS MEDIA BACTERIAL			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIRECTAL ABSCESS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS BACTERIAL			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMOCYSTIS JIROVECII PNEUMONIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	7 / 254 (2.76%)	5 / 24 (20.83%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
PNEUMONIA BORDETELLA			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
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 KLEBSIELLA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA LEGIONELLA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA PRIMARY ATYPICAL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 PSEUDOMONAL			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA STREPTOCOCCAL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 VIRAL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTOPERATIVE WOUND INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS ACUTE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 TRACT INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC SHOCK			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUSITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SKIN INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 INFECTION			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBCUTANEOUS ABSCESS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 254 (1.18%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	3 / 254 (1.18%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
UROSEPSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 DIARRHOEA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 INFECTION			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 2	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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 STAPHYLOCOCCAL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
DECREASED APPETITE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIABETES MELLITUS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FLUID OVERLOAD			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GOUT			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (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
HYPERKALAEMIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERLIPIDAEMIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOKALAEMIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
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	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPOVOLAEMIA			

subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Renal	Pancreas-Kidney	Liver
Total subjects affected by non-serious adverse events			
subjects affected / exposed	166 / 701 (23.68%)	5 / 8 (62.50%)	6 / 18 (33.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
HEAD AND NECK CANCER			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
SKIN CANCER			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
MALAISE			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	36 / 701 (5.14%)	1 / 8 (12.50%)	1 / 18 (5.56%)
occurrences (all)	38	1	1
PYREXIA			

subjects affected / exposed	9 / 701 (1.28%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	10	0	0
Immune system disorders			
TRANSPLANT REJECTION			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
DYSPNOEA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Investigations			
BLOOD CREATININE INCREASED			
subjects affected / exposed	17 / 701 (2.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	18	0	0
BLOOD TESTOSTERONE DECREASED			
subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	6	0	0
Injury, poisoning and procedural complications			
EPICONDYLITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
FALL			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
GRAFT THROMBOSIS			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
TRAUMATIC HAEMATOMA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1

Cardiac disorders			
ATRIAL TACHYCARDIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	14 / 701 (2.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	16	0	0
LEUKOPENIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
THROMBOCYTOPENIA			
subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	5	0	2
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
APHTHOUS STOMATITIS			

subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
GINGIVAL ULCERATION			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
GINGIVITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
MOUTH ULCERATION			
subjects affected / exposed	5 / 701 (0.71%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	5	0	1
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
SKIN ULCER			
subjects affected / exposed	2 / 701 (0.29%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Renal and urinary disorders			
KIDNEY FIBROSIS			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
PROTEINURIA			
subjects affected / exposed	21 / 701 (3.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	21	0	0
RENAL FAILURE CHRONIC			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
RENAL IMPAIRMENT			
subjects affected / exposed	2 / 701 (0.29%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
OSTEOPENIA			

subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Infections and infestations			
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
H1N1 INFLUENZA			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
HERPES ZOSTER			
subjects affected / exposed	3 / 701 (0.43%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	3	1	0
NASOPHARYNGITIS			
subjects affected / exposed	3 / 701 (0.43%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	1 / 701 (0.14%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
PSEUDOMONAS BRONCHITIS			
subjects affected / exposed	0 / 701 (0.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	3 / 701 (0.43%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	4	1	0
UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	5 / 701 (0.71%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	6	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	19 / 701 (2.71%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	26	1	0
VIRAL INFECTION			
subjects affected / exposed	1 / 701 (0.14%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
DYSLIPIDAEMIA			
subjects affected / exposed	21 / 701 (3.00%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	21	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	4 / 701 (0.57%)	0 / 8 (0.00%)	2 / 18 (11.11%)
occurrences (all)	4	0	2
HYPERLIPIDAEMIA			
subjects affected / exposed	25 / 701 (3.57%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	25	0	0
IRON DEFICIENCY			
subjects affected / exposed	1 / 701 (0.14%)	0 / 8 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
TYPE 1 DIABETES MELLITUS			
subjects affected / exposed	0 / 701 (0.00%)	1 / 8 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Heart	Lung/Heart-Lung	Pediatric Renal
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 254 (25.59%)	11 / 24 (45.83%)	5 / 19 (26.32%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	2 / 254 (0.79%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	4	1	0
HEAD AND NECK CANCER			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
SKIN CANCER			

subjects affected / exposed	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	9 / 254 (3.54%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	9	0	0
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	2 / 254 (0.79%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
MALAISE			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
OEDEMA PERIPHERAL			
subjects affected / exposed	17 / 254 (6.69%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	18	0	0
PYREXIA			
subjects affected / exposed	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Immune system disorders			
TRANSPLANT REJECTION			
subjects affected / exposed	2 / 254 (0.79%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	7 / 254 (2.76%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences (all)	7	2	0
DYSPNOEA			
subjects affected / exposed	1 / 254 (0.39%)	2 / 24 (8.33%)	0 / 19 (0.00%)
occurrences (all)	1	3	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Investigations			
BLOOD CREATININE INCREASED			

subjects affected / exposed	4 / 254 (1.57%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	4	0	0
BLOOD TESTOSTERONE DECREASED			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
EPICONDYLITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
GRAFT THROMBOSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
TRAUMATIC HAEMATOMA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ATRIAL TACHYCARDIA			
subjects affected / exposed	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	2 / 254 (0.79%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	2	1	0
SUBARACHNOID HAEMORRHAGE			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

ANAEMIA			
subjects affected / exposed	8 / 254 (3.15%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	9	1	0
LEUKOPENIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
THROMBOCYTOPENIA			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
EAR PAIN			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
APHTHOUS STOMATITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	6
GINGIVAL ULCERATION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
GINGIVITIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
MOUTH ULCERATION			
subjects affected / exposed	5 / 254 (1.97%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	6	0	0
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
SKIN ULCER			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

KIDNEY FIBROSIS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
PROTEINURIA			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
RENAL FAILURE CHRONIC			
subjects affected / exposed	4 / 254 (1.57%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	4	1	0
RENAL IMPAIRMENT			
subjects affected / exposed	9 / 254 (3.54%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	9	0	0
Musculoskeletal and connective tissue disorders			
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
OSTEOPENIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ESCHERICHIA URINARY TRACT INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
H1N1 INFLUENZA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
HERPES ZOSTER			
subjects affected / exposed	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
ONYCHOMYCOSIS			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
ORAL HERPES			

subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
OTITIS MEDIA			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
PSEUDOMONAS BRONCHITIS			
subjects affected / exposed	0 / 254 (0.00%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
SINUSITIS			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	9 / 254 (3.54%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	9	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 254 (0.39%)	0 / 24 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	2
VIRAL INFECTION			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
DYSLIPIDAEMIA			
subjects affected / exposed	2 / 254 (0.79%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	5 / 254 (1.97%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	6	0	0
HYPERLIPIDAEMIA			
subjects affected / exposed	20 / 254 (7.87%)	0 / 24 (0.00%)	2 / 19 (10.53%)
occurrences (all)	20	0	2
IRON DEFICIENCY			

subjects affected / exposed	1 / 254 (0.39%)	1 / 24 (4.17%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
TYPE 1 DIABETES MELLITUS			
subjects affected / exposed	0 / 254 (0.00%)	0 / 24 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 October 2003	Amendment 1: The protocol was amended to revise the inclusion and exclusion criteria to remove reference to concomitant treatment with Neoral, and to clarify when the study will end.
19 April 2005	Amendment 2: A global amendment to extend the trial from 24 to 48 months. In addition, a six month visit was added for patients who participated in a previous RAD001 (everolimus) trial with a duration of less than 12 months. Lastly, the visit schedule was amended to include evaluations of sexual maturity for children participating in the trial.
19 November 2008	Amendment 3: A global amendment to extend the trial from 48 to 72 months and to provide detailed treatment guidelines for the investigator as well as include possible everolimus drug interactions.
12 January 2011	Amendment 5: A global amendment to extend the trial from 96 months to 120 months for patients who have already reached Month 96 so they are able to continue to receive Certican/Zortress up to the time it becomes commercially available in the given indication, reimbursed by appropriate payors or the project has been discontinued whichever comes first. In addition, the Background section, Administrative Procedures, Appendices 1, 2 and 4 were updated to reflect new Novartis template language and new information from the most recent Investigator's Brochure.
06 June 2011	Amendment 6: This amendment was to extend the study from Month 96 to Month 120 so that patients were able to continue to receive everolimus (Certican/Zortress) up to the time it became commercially available in the given indication, reimbursed by appropriate payors or the project was discontinued whichever came first.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported