Clinical trial results:
An Open-label, Randomized, Controlled, Multicenter, Phase I/II Trial Investigating 2 EMD 525797 Doses in Combination With Cetuximab and Irinotecan Versus Cetuximab and Irinotecan Alone, as Second-line Treatment for Subjects With K-ras Wild Type (WT) Metastatic Colorectal Cancer (mCRC)

Summary

EudraCT number	2009-012040-16
Trial protocol	DE BE CZ GB HU GR BG
Global end of trial date	28 April 2015

Results information

Result version number	v2 (current)
This version publication date	25 June 2016
First version publication date	08 May 2016
Version creation reason	• Correction of full data set Correction of full data set

Trial information

Trial identification

Sponsor protocol code	EMR62242-004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01008475
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Serono, a division of Merck KGaA
Sponsor organisation address	Frankfurter Strasse 250, Darmstadt, Germany, 64293
Public contact	Merck KGaA, Merck Serono, a division of Merck KGaA, Communication Centre Merck KGaA, 49 6151725200, service@merckgroup.com
Scientific contact	Merck KGaA, Merck Serono, a division of Merck KGaA, Communication Centre Merck KGaA, 49 6151725200, service@merckgroup.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 April 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 April 2015
Global end of trial reached?	Yes
Global end of trial date	28 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To characterize the safety and tolerability profile of repeated administration of different EMD 525797 (abituzumab) dose levels in combination with cetuximab and irinotecan in subjects with k-ras WT mCRC after failure of first-line therapy with an oxaliplatin-containing regimen.
- To assess the anticancer activity of 2 abituzumab doses in terms of progression-free survival time in subjects with k-ras WT mCRC after failure of first-line therapy with an oxaliplatin-containing regimen.

Protection of trial subjects:

Subject protection was ensured by following high medical and ethical standards in accordance with the principles laid down in the Declaration of Helsinki, and that are consistent with Good Clinical Practice and applicable regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2009
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	Germany: 25
Country: Number of subjects enrolled	Czech Republic: 61
Country: Number of subjects enrolled	United Kingdom: 20
Country: Number of subjects enrolled	Spain: 39
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	Cyprus: 1
Country: Number of subjects enrolled	Bulgaria: 5
Country: Number of subjects enrolled	Hungary: 19
Country: Number of subjects enrolled	Poland: 7
Country: Number of subjects enrolled	Russian Federation: 49
Worldwide total number of subjects	232
EEA total number of subjects	181

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	155
From 65 to 84 years	77
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

This study consists of two parts, safety part and randomized part. A total of 16 subjects were included in the safety part and 216 subjects were included in the randomized part of the study. The subjects who participated in the safety part of the study were not included in the randomized part of the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Safety part: EMD 525797 250 mg + SoC

Arm description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 250 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cetuximab 400 mg/m^2 was administered on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly.

Investigational medicinal product name	Abituzumab
Investigational medicinal product code	EMD 525797
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

EMD 525797 250 mg was administered as a 1 -hour IV infusion for every 2 weeks.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan 180 mg/m^2 was administered as a IV infusion for 30-90 minutes for every 2 weeks.

Arm title	Safety part: EMD 525797 500 mg + SoC

Arm description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2

hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cetuximab 400 mg/m^2 was administered on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly.

Investigational medicinal product name	Abituzumab
Investigational medicinal product code	EMD 525797
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

EMD 525797 500 mg was administered as a 1 -hour IV infusion for every 2 weeks.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan 180 mg/m^2 was administered as a IV infusion for 30-90 minutes for every 2 weeks.

Arm title	Safety part: EMD525797 750 mg + SoC

Arm description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 750 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cetuximab 400 mg/m^2 was administered on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly.

Investigational medicinal product name	Abituzumab
Investigational medicinal product code	EMD 525797
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

EMD 525797 750 mg was administered as a 1 -hour IV infusion for every 2 weeks.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan 180 mg/m^2 was administered as a IV infusion for 30-90 minutes for every 2 weeks.

Arm title	Safety part: EMD 525797 1000 mg +SoC

Arm description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cetuximab 400 mg/m^2 was administered on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly.

Investigational medicinal product name	Abituzumab
Investigational medicinal product code	EMD 525797
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

EMD 525797 1000 mg was administered as a 1 -hour IV infusion for every 2 weeks.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan 180 mg/m^2 was administered as a IV infusion for 30-90 minutes for every 2 weeks.

Arm title	Randomized Part: Standard of Care (SoC)

Arm description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Arm type	Control
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cetuximab 400 mg/m^2 was administered on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan 180 mg/m^2 was administered as a IV infusion for 30-90 minutes for every 2 weeks.

Arm title	Randomized part: EMD 525797 500 mg + SoC

Arm description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cetuximab 400 mg/m^2 was administered on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly.

Investigational medicinal product name	Abituzumab
Investigational medicinal product code	EMD 525797
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

EMD 525797 500 mg was administered as a 1 -hour IV infusion for every 2 weeks.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan 180 mg/m^2 was administered as a IV infusion for 30-90 minutes for every 2 weeks.

Arm title	Randomized Part: EMD 525797 1000 mg + SoC

Arm description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Cetuximab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Cetuximab 400 mg/m^2 was administered on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and

then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Irinotecan 180 mg/m^2 was administered as a IV infusion for 30-90 minutes for every 2 weeks.

Investigational medicinal product name	Abituzumab
Investigational medicinal product code	EMD 525797
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

EMD 525797 1000 mg was administered as a 1 -hour IV infusion for every 2 weeks.

Number of subjects in period 1	Safety part: EMD 525797 250 mg + SoC	Safety part: EMD 525797 500 mg + SoC	Safety part: EMD525797 750 mg + SoC
Started	3	3	7
Completed	3	3	7
Not completed	0	0	0
Ongoing treatment at data cut-off date	-	-	-
Subject randomized to 1000 mg group received SoC	-	-	-

Number of subjects in period 1	Safety part: EMD 525797 1000 mg +SoC	Randomized Part: Standard of Care (SoC)	Randomized part: EMD 525797 500 mg + SoC
Started	3	72	73
Completed	3	67	67
Not completed	0	5	6
Ongoing treatment at data cut-off date	-	5	5
Subject randomized to 1000 mg group received SoC	-	-	1

Number of subjects in period 1	Randomized Part: EMD 525797 1000 mg + SoC
Started	71
Completed	67
Not completed	4
Ongoing treatment at data cut-off date	4
Subject randomized to 1000 mg group received SoC	-

Reporting groups

Reporting group title	Safety part: EMD 525797 250 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 250 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Safety part: EMD 525797 500 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Safety part: EMD525797 750 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 750 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Safety part: EMD 525797 1000 mg +SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Randomized Part: Standard of Care (SoC)

Reporting group description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Randomized part: EMD 525797 500 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Randomized Part: EMD 525797 1000 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group values	Safety part: EMD 525797 250 mg + SoC	Safety part: EMD 525797 500 mg + SoC	Safety part: EMD525797 750 mg + SoC
Number of subjects	3	3	7
Age categorical Units: Subjects			
Age Continuous Units: Years			
arithmetic mean	62.3	57.7	60.4
standard deviation	± 11.5	± 11.2	± 6.2
Gender, Male/Female Units: Subjects			
Female	2	1	4
Male	1	2	3

Reporting group values	Safety part: EMD 525797 1000 mg +SoC	Randomized Part: Standard of Care (SoC)	Randomized part: EMD 525797 500 mg + SoC
Number of subjects	3	72	73
Age categorical Units: Subjects			
Age Continuous Units: Years			
arithmetic mean	63	56.2	58.9
standard deviation	± 7.2	± 12.11	± 12.18
Gender, Male/Female Units: Subjects			
Female	2	27	36
Male	1	45	37

Reporting group values	Randomized Part: EMD 525797 1000 mg + SoC	Total	
Number of subjects	71	232	
Age categorical Units: Subjects			
Age Continuous Units: Years			
arithmetic mean	59.9		
standard deviation	± 10.63	-	
Gender, Male/Female Units: Subjects			
Female	23	95	
Male	48	137	

End points

End points reporting groups

Reporting group title	Safety part: EMD 525797 250 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 250 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Safety part: EMD 525797 500 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Safety part: EMD525797 750 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 750 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Safety part: EMD 525797 1000 mg +SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Randomized Part: Standard of Care (SoC)

Reporting group description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Randomized part: EMD 525797 500 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	Randomized Part: EMD 525797 1000 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Safety part: EMD 525797 250 mg + Standard of Care (SoC)
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 once weekly followed by EMD 525797 at a target dose of 250 mg as a 1-hour IV infusion for every 2 weeks, followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Safety part: EMD 525797 750 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 once weekly followed by EMD 525797 at a target dose of 750 mg as a 1-hour IV infusion for every 2 weeks, followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Safety part: EMD 525797 1000 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 once weekly followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Randomized part: SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Randomized part: EMD 525797 1000 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Safety Part: EMD 525797 250 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 250 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Safety Part: EMD 525797 500 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented

progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Safety Part: EMD525797 750 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 750 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Safety Part: EMD 525797 1000 mg +SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	Standard of Care (SoC)
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radiographically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	EMD 525797 500 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radiographically documented PD (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Subject analysis set title	EMD 525797 1000 mg + SoC
Subject analysis set type	Full analysis

Subject analysis set description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Primary: Safety Part: Number of subjects experiencing DLTs (dose limiting toxicity)

End point title	Safety Part: Number of subjects experiencing DLTs (dose limiting toxicity)[1]

End point description:

DLT :any Grade 4 hematologic toxicity/ Grade 3/4 non-hematologic toxicity assessed as related to trial treatment by Investigator &/or Sponsor & confirmed by safety monitoring committee (SMC) to be relevant to combination treatment within 1 cycle of therapy. Any Grade 3/ 4 non haematological toxicity,any Grade 4 hematological toxicity,treatment related deaths within first 2 weeks of therapy.Toxicities excluded from DLT: alopecia,rash,nausea,vomiting & hypomagnesemia of Grade 3/ 4 severity,Grade 4 neutropenia/ leukopenia lasting for =< 5 days & not associated with fever; Single lab values out of normal range without any clinical correlation & resolve within 7 days; Grade 3 or 4 diarrhoea without adequate supportive care. Adequate supportive care has been administered & Grade 4 diarrhoea persists (investigator decision); isolated Grade 4 lymphocytopenia and thrombocytopenia without clinical correlation. Dose-escalation analysis set was used for the evaluation of the endpoint.

End point type	Primary

End point timeframe:

Time from the first dose of study drug up to 2 weeks

Notes:

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

End point values	Safety Part: EMD 525797 250 mg + SoC	Safety Part: EMD 525797 500 mg + SoC	Safety Part: EMD525797 750 mg + SoC	Safety Part: EMD 525797 1000 mg +SoC
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	3	7	3
Units: subjects				
number (not applicable)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Randomized Part: Progression free survival (PFS)

End point title	Randomized Part: Progression free survival (PFS)

End point description:

PFS:the time from the randomization date to first documented sign of objective radio-graphic disease progression (PD) as per Response Evaluation Criteria In Solid Tumors version 1. (RECIST 1.0) or death from any cause if reported within 12 weeks from last tumor assessment. PD per RECIST v 1.0 was defined as at least 20% increase in sum of longest diameter of target lesions, taking as the reference smallest sum of longest diameters recorded since treatment started, or unequivocal progression of existing non-target lesion or appearance of new lesions. Subjects who did not progress or died at the time of analyses, or subjects who died without previously radio-graphically documented PD and death was observed after more than 12 weeks of last tumor assessment without progression, these subjects were censored at their last tumor assessment date or date of randomization, whichever occurred last. Intention-to-treat (ITT) analysis set: all the subjects who were randomized into treatment groups.

End point type	Primary

End point timeframe:

Time from randomization until progressive disease or death; assessed up to 18 months (i.e data cut-off date: 09 Oct 2013)

End point values	Standard of Care (SoC)	EMD 525797 500 mg + SoC	EMD 525797 1000 mg + SoC	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	73	71	
Units: months				
median (confidence interval 95%)	5.6 (4.2 to 6.9)	5.4 (4.1 to 6)	5.6 (4.1 to 6.9)	

Statistical analyses

Statistical analysis title	SoC vs EMD 525797 500 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 500 mg + SoC
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.64

Statistical analysis title	SoC vs EMD 525797 1000 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 1000 mg + SoC
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.61

Secondary: Overall survival (OS) time	
End point title	Overall survival (OS) time

End point description:

OS was defined as the time from the date of randomization to the date of death from any cause. For subjects who were still alive at the analysis cut off date or lost to follow up, survival was censored at the last recorded date the subject was known to be alive or at the analysis cut off date, whichever occurred first. ITT analysis set included all the subjects who were randomized into the trial.

End point type	Secondary

End point timeframe:

Time from randomization until death assessed up to 18 months (i.e data cut-off date: 09 Oct 2013)

End point values	Standard of Care (SoC)	EMD 525797 500 mg + SoC	EMD 525797 1000 mg + SoC	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	73	71	
Units: months				
median (confidence interval 95%)	11.6 (9.8 to 15.7)	15 (10.9 to 19.2)	14.4 (9.8 to 19.3)	

Statistical analyses

Statistical analysis title	SoC vs EMD 525797 500 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 500 mg + SoC
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.28

Statistical analysis title	SoC vs EMD 525797 1000 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 1000 mg + SoC
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	1.25

Secondary: Time to progression (TTP)

End point title	Time to progression (TTP)

End point description:

TTP was defined as the time from the date of randomization to the date of objective radiographic disease progression (PD). PD per RECIST v 1.0 was defined as at least 20% increase in the sum of the longest diameter of target lesions, taking as the reference the smallest sum of longest diameters recorded since treatment started, or unequivocal progression of existing non-target lesion or appearance of new lesions. For subjects who did not progress or who were without any post baseline tumor assessment, TTP was censored at their last tumor assessment date, or at the randomization date, whichever occurred last. ITT analysis set included all the subjects who were randomized into the trial.

End point type	Secondary

End point timeframe:

Time from randomization until disease progression assessed up to 18 months (i.e data cut-off date: 09 Oct 2013)

End point values	Standard of Care (SoC)	EMD 525797 500 mg + SoC	EMD 525797 1000 mg + SoC	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	73	71	
Units: months				
median (confidence interval 95%)	5.8 (4.4 to 7.2)	5.6 (4.2 to 8.3)	6.5 (4.2 to 7.1)	

Statistical analyses

Statistical analysis title	SoC vs EMD 525797 500 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 500 mg + SoC
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.65

Statistical analysis title	SoC vs EMD 525797 1000 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 1000 mg + SoC
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.65

Secondary: Number of subjects with Tumor response

End point title	Number of subjects with Tumor response

End point description:

Tumor response was defined as the presence of at least 1 confirmed complete response (CR) or confirmed partial response (PR) as judged by RECIST version 1.0. CR was defined for target lesions

(TLs) as the disappearance of all lesions, and for non-target lesions (NTLs) as the disappearance of all non-target non-measurable lesions and/or normalization of serum levels of tumor markers. PR was defined for TLs as at least a 30 percent (%) decrease from baseline (BL) in the sum of longest diameter (SLD) of TLs. ITT analysis set included all the subjects who were randomized into the trial.

End point type	Secondary

End point timeframe:

Time from randomization up to 18 months (i.e data cut-off date: 09 Oct 2013)

End point values	Standard of Care (SoC)	EMD 525797 500 mg + SoC	EMD 525797 1000 mg + SoC	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	73	71	
Units: Subjects				
number (not applicable)				
CR	2	1	0	
PR	17	19	18	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to treatment failure (TTF)

End point title	Time to treatment failure (TTF)

End point description:

TTF was defined as the time from randomization to treatment discontinuation for any reason. For subjects on drug at the analysis cut off date or lost to follow up, TTF was censored at the trial discontinuation date or at the analysis cut off date, whichever occurred first. ITT analysis set included all the subjects who were randomized into the trial.

End point type	Secondary

End point timeframe:

Time from randomization until discontinuation assessed up to 18 months (i.e data cut-off date: 09 Oct 2013)

End point values	Standard of Care (SoC)	EMD 525797 500 mg + SoC	EMD 525797 1000 mg + SoC	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	72	73	71	
Units: months				
median (confidence interval 95%)	5.2 (4.4 to 6.2)	4.3 (3.6 to 6.1)	4.8 (3.3 to 6.6)	

Statistical analyses

Statistical analysis title	SoC vs EMD 525797 500 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 500 mg + SoC
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.34

Statistical analysis title	SoC vs EMD 525797 1000 mg + SoC
Comparison groups	Standard of Care (SoC) v EMD 525797 1000 mg + SoC
Number of subjects included in analysis	143
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Cox proportional hazard
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.48

Adverse events information

Timeframe for reporting adverse events:

From the first dose of study drug administration up to 50 days after the last dose of study drug administration

Adverse event reporting additional description:

The safety analysis set included all subjects who received at least 1 dose of the trial medication. 1 subject who was randomized to EMD525797 1000 mg group received only SoC, therefore this subjects was reported under the SOC group.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	Safety Part: EMD 525797 250 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 250 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator’s assessment), or withdrawal of consent.

Reporting group title	Safety Part: EMD 525797 500 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator’s assessment), or withdrawal of consent.

Reporting group title	Safety Part: EMD525797 750 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 750 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator’s assessment), or withdrawal of consent.

Reporting group title	Safety Part: EMD 525797 1000 mg +SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator’s assessment), or withdrawal of consent.

Reporting group title	Standard of Care (SoC)

Reporting group description:

Cetuximab was administered at a dose of 400 milligram per square meter (mg/m^2) on Day 1 Cycle 1 (Week 1) as intravenous (IV) infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly followed by irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radiographically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator’s assessment), or withdrawal of consent.

Reporting group title	EMD 525797 500 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2

hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 500 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radiographically documented PD (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Reporting group title	EMD 525797 1000 mg + SoC

Reporting group description:

Cetuximab was administered at a dose of 400 mg/m^2 on Day 1 Cycle 1 (Week 1) as IV infusion for 2 hours, and then at a dose of 250 mg/m^2 on Day 8 (Week 2) once weekly; followed by EMD 525797 at a target dose of 1000 mg as a 1-hour IV infusion for every 2 weeks, followed by Irinotecan at a dose of 180 mg/m^2 as IV infusion for 30-90 minutes for every 2 weeks until radio-graphically documented progressive disease (PD) (as assessed by the investigator), unacceptable toxicity or eligibility for curative resection (investigator's assessment), or withdrawal of consent.

Serious adverse events	Safety Part: EMD 525797 250 mg + SoC	Safety Part: EMD 525797 500 mg + SoC	Safety Part: EMD525797 750 mg + SoC
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	3 / 7 (42.86%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events			
Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous Thrombosis Limb			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Thrombosis Prophylaxis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Asthenia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Malfunction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease Progression			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Physical Health Deterioration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Mucosal Inflammation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Multi-Organ Failure			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance Status Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Shock			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Bronchospasm			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Exertional			

alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Blood Bilirubin Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulation Factor Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-Glutamyltransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Physical Condition Abnormal			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Femoral Neck Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Atrial Fibrillation			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Acute			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachyarrhythmia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular Accident			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Neutropenia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Hernia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic Obstruction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Constipation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Stenosis alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Toxicity alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Ulcer Haemorrhage alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Perforation alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Failure			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Cholestatic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash Maculo-Papular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic Skin Eruption			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Renal Failure			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Acute			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Inappropriate Antidiuretic Hormone Secretion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
Neck Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Wall Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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 Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic Shock			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cachexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased Appetite			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Safety Part: EMD 525797 1000 mg +SoC	Standard of Care (SoC)	EMD 525797 500 mg + SoC
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	30 / 73 (41.10%)	27 / 72 (37.50%)
number of deaths (all causes)	0	45	39
number of deaths resulting from adverse events		6	
Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous Thrombosis Limb			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
Thrombosis Prophylaxis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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 Malfunction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease Progression			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	2 / 72 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General Physical Health Deterioration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal Inflammation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance Status Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	2 / 72 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Shock			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
Bronchospasm			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea Exertional			

alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	5 / 73 (6.85%)	0 / 72 (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
Respiratory Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood Bilirubin Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood Creatinine Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulation Factor Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-Glutamyltransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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 Physical Condition Abnormal			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil Count Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
Femoral Neck Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial Fibrillation			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Failure Acute			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Tachyarrhythmia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
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			
Cerebrovascular Accident			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Coma			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Neutropenia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	3 / 72 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 3	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Hernia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Abdominal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic Obstruction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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 alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Stenosis alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Toxicity alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Ulcer Haemorrhage alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Intestinal Obstruction alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Intestinal Perforation alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periodontitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	2 / 72 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Failure			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice Cholestatic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash Maculo-Papular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic Skin Eruption			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal Failure			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Failure Acute			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
Neck Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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 Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Wall Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device Related Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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 Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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 Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
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			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic Shock			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	1 / 73 (1.37%)	0 / 72 (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
Metabolism and nutrition disorders			
Cachexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased Appetite			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte Imbalance			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	EMD 525797 1000 mg + SoC		
Total subjects affected by serious adverse events			
subjects affected / exposed	34 / 69 (49.28%)		
number of deaths (all causes)	35		
number of deaths resulting from adverse events			
Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Venous Thrombosis Limb			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Thrombosis Prophylaxis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Death				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	1 / 1			
Device Malfunction				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disease Progression				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Fatigue				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General Physical Health Deterioration				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mucosal Inflammation				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Multi-Organ Failure				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Performance Status Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Anaphylactic Shock				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Bronchospasm				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea Exertional				

alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary Embolism				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Respiratory Disorder				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory Failure				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood Bilirubin Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood Creatinine Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coagulation Factor Increased				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gamma-Glutamyltransferase Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General Physical Condition Abnormal				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutrophil Count Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Femoral Neck Fracture				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Overdose				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial Fibrillation				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Failure Acute				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachyarrhythmia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebrovascular Accident				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coma				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polyneuropathy				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile Neutropenia				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	3 / 69 (4.35%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Leukopenia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal Hernia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	5 / 69 (7.25%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Ascites				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colonic Obstruction				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Constipation				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	7 / 69 (10.14%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Enteritis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterovesical Fistula				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Gastrointestinal Haemorrhage				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Stenosis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Toxicity				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Ulcer Haemorrhage				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal Obstruction				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intestinal Perforation				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Nausea				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	2 / 69 (2.90%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Periodontitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subileus				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic Failure				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice Cholestatic				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Rash				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash Maculo-Papular				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Toxic Skin Eruption				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Renal Failure				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal Failure Acute				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Inappropriate Antidiuretic Hormone Secretion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Neck Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pathological Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal Wall Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device Related Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Device Related Sepsis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal Abscess				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	1 / 1			
Septic Shock				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Cachexia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Decreased Appetite				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Diabetes Mellitus				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrolyte Imbalance				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperkalaemia				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Safety Part: EMD 525797 250 mg + SoC	Safety Part: EMD 525797 500 mg + SoC	Safety Part: EMD525797 750 mg + SoC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	7 / 7 (100.00%)
Vascular disorders			
Aortic Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Circulatory Collapse			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flushing			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematoma			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypotension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Orthostatic Hypotension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pallor			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral Ischaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Venous Insufficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Venous Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	3 / 7 (42.86%)
occurrences (all)	0	2	3
Catheter Site Erythema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Catheter Site Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Extravasation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative dictionary used:			

MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Feeling Cold			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General Physical Health Deterioration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Impaired Healing			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection Site Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised Oedema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal Inflammation			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 7 (42.86%)
occurrences (all)	1	0	3
Non-Cardiac Chest Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Performance Status Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Secretion Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Xerosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Immune system disorders			
Contrast Media Allergy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Drug Hypersensitivity			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypersensitivity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Breast Mass			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Breast Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematospermia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Pruritus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthmatic Crisis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchial Secretion Retention			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysphonia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea Exertional			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Haemoptysis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Hypoxia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal Dryness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Obstructive Airways Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Productive Cough			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary Embolism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary Toxicity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory Disorder			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis Allergic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sputum Discoloured			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Throat Irritation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Anxiety			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Confusional State			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decreased Interest			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depressed Mood			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depressive Symptom			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Emotional Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated Partial Thromboplastin Time			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Activated Partial Thromboplastin Time Prolonged			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	5	0	0
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Aspartate Aminotransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood Alkaline Phosphatase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Bilirubin Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood Glucose Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Iron Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Magnesium Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Pressure Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Thyroid Stimulating Hormone Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Body Temperature Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
C-Reactive Protein Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Creatinine Renal Clearance Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ejection Fraction Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T Wave Inversion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eosinophil Count Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-Glutamyltransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematocrit Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Haemoglobin Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
International Normalised Ratio Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neutrophil Count Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet Count Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red Blood Cell Count Decreased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Thrombin Time Prolonged			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Transaminases Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Urine Output Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Weight Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contrast Media Reaction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Head Injury			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Incisional Hernia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion Related Reaction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post Procedural Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post Procedural Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radius Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sunburn			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Suture Related Complication			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Wound			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Congenital Hair Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trichomegaly			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina Pectoris			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Atrial Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Left Ventricular Dysfunction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myocardial Ischaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Right Ventricular Dysfunction			

alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular Extrasystoles			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ventricular Extrasystoles			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cholinergic Syndrome			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Diabetic Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Dizziness Postural			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epilepsy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatic Encephalopathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypogeusia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lethargy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Neuropathy Peripheral			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral Motor Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensory Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Polyneuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Radiculitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sciatica			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Speech Disorder			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toxic Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual Field Defect			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Agranulocytosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Anaemia Of Malignant Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Aplastic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Granulocytopenia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypochromic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iron Deficiency Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	9	0	0
Leukopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	3 / 7 (42.86%)
occurrences (all)	3	1	6
Lymphadenitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Microcytic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Normochromic Normocytic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Splenic Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
External Ear Inflammation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vertigo Positional			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dry Eye			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema Of Eyelid			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid Oedema			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelids Pruritus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Meibomianitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Miosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular Hyperaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ocular Icterus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Visual Acuity Reduced			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Abdominal Pain Lower			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain Upper			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal Tenderness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal Haemorrhage			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anorectal Discomfort			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphthous Stomatitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Ascites			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Diarrhoea			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	4 / 7 (57.14%)
occurrences (all)	2	0	10
Dry Mouth			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Dyspepsia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Enteritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Enterovesical Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faecal Vomiting			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Food Poisoning			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Frequent Bowel Movements			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis Erosive			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Motility Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Toxicity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Sphincter Insufficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival Bleeding			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Haemorrhoids			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intestinal Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intestinal Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intestinal Villi Atrophy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mesenteric Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucous Stools			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nausea			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	5	4	2
Odynophagia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pancreatitis Acute			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia Oral			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periodontal Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Proctalgia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Rectal Tenesmus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Subileus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tongue Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth Discolouration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Hepatobiliary disorders			

Biliary Colic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hepatic Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Jaundice			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	6
Alopecia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Dermal Cyst			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis Acneiform			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 7 (42.86%)
occurrences (all)	3	0	7
Dermatitis Allergic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis Atopic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Drug Eruption			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry Skin			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Eczema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Erythema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Exfoliative Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ingrowing Nail			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Nail Toxicity			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Palmar-Plantar Erythrodysaesthesia Syndrome			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Panniculitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Penile Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Petechiae			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pigmentation Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prurigo			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pruritus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Pruritus Generalised			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	3 / 3 (100.00%)	1 / 7 (14.29%)
occurrences (all)	4	5	3
Rash Generalised			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash Maculo-Papular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash Pruritic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash Vesicular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Chapped			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Erosion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Exfoliation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Fissures			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Skin Irritation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin Ulcer			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Subcutaneous Nodule			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toxic Skin Eruption			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Anuria			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glycosuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Leukocyturia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nephrolithiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oliguria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Polyuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Renal Colic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urethral Obstruction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Flank Pain			

alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Groin Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Inguinal Mass			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Joint Swelling			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mobility Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle Twitching			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Osteoporosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pain In Extremity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Soft Tissue Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Synovitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
Abdominal Wall Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter Site Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cystitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Device Related Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Escherichia Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Furuncle			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Viral			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Genital Candidiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Herpes Zoster			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected Skin Ulcer			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Keratitis Herpetic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised Infection			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lung Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lyme Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail Bed Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal Candidiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral Candidiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral Fungal Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oral Herpes			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis Externa			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Postoperative Wound Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulpitis Dental			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash Pustular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Severe Acute Respiratory Syndrome			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Streptococcal Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Subcutaneous Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tinea Pedis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Viral Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Mycotic Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Decreased Appetite			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 7 (42.86%)
occurrences (all)	1	1	3
Dehydration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diabetes Mellitus			
alternative dictionary used:			

MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	5	1	1
Hyponatraemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Iron Deficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Plasma Protein Metabolism Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Safety Part: EMD 525797 1000 mg +SoC	Standard of Care (SoC)	EMD 525797 500 mg + SoC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	72 / 73 (98.63%)	72 / 72 (100.00%)
Vascular disorders			
Aortic Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Circulatory Collapse			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Flushing			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Haematoma			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	3
Hypertension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	2 / 72 (2.78%)
occurrences (all)	0	3	2
Hypotension			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	2 / 72 (2.78%)
occurrences (all)	0	2	3
Orthostatic Hypotension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Pallor			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Peripheral Ischaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Phlebitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Thrombophlebitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	2
Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Venous Insufficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Venous Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0

General disorders and administration site conditions			
Asthenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	9 / 73 (12.33%)	15 / 72 (20.83%)
occurrences (all)	1	15	26
Catheter Site Erythema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Catheter Site Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Chest Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Chills			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Extravasation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Fatigue			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	15 / 73 (20.55%)	16 / 72 (22.22%)
occurrences (all)	0	21	26
Feeling Cold			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
General Physical Health Deterioration			
alternative dictionary used:			

MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Impaired Healing			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Influenza Like Illness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences (all)	0	1	2
Injection Site Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Localised Oedema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Malaise			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Mucosal Inflammation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Non-Cardiac Chest Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Oedema Peripheral			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	4 / 72 (5.56%)
occurrences (all)	0	4	5
Performance Status Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	4 / 73 (5.48%)	13 / 72 (18.06%)
occurrences (all)	1	5	23
Secretion Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Xerosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2
Immune system disorders			
Contrast Media Allergy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Drug Hypersensitivity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Hypersensitivity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Balanitis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Breast Mass			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Breast Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Haematospermia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Pelvic Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Vulvovaginal Pruritus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthmatic Crisis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Bronchial Secretion Retention			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Cough			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	7 / 73 (9.59%)	6 / 72 (8.33%)
occurrences (all)	0	8	6
Dysphonia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	0 / 72 (0.00%)
occurrences (all)	0	4	0
Dyspnoea			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	0 / 72 (0.00%)
occurrences (all)	0	3	0
Dyspnoea Exertional			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	4 / 72 (5.56%)
occurrences (all)	0	3	5
Epistaxis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	7 / 73 (9.59%)	5 / 72 (6.94%)
occurrences (all)	2	8	6
Haemoptysis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences (all)	0	1	2
Hiccups			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1

Nasal Dryness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Obstructive Airways Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Productive Cough			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Pulmonary Embolism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Pulmonary Toxicity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Respiratory Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	4
Rhinitis Allergic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Sputum Discoloured			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Throat Irritation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Psychiatric disorders			
Agitation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Anxiety			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	2 / 73 (2.74%)	1 / 72 (1.39%)
occurrences (all)	1	4	1
Confusional State			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Decreased Interest			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Depressed Mood			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Depression			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Depressive Symptom			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Emotional Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Insomnia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	2 / 72 (2.78%)
occurrences (all)	0	2	2
Investigations			
Activated Partial Thromboplastin Time			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Activated Partial Thromboplastin Time Prolonged			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	4 / 72 (5.56%)
occurrences (all)	0	2	4
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	12 / 73 (16.44%)	4 / 72 (5.56%)
occurrences (all)	1	22	5
Aspartate Aminotransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	8 / 73 (10.96%)	4 / 72 (5.56%)
occurrences (all)	0	9	4
Blood Alkaline Phosphatase Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	4 / 73 (5.48%)	2 / 72 (2.78%)
occurrences (all)	1	7	3
Blood Bilirubin Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Blood Glucose Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Blood Iron Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Blood Lactate Dehydrogenase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	3 / 72 (4.17%)
occurrences (all)	0	1	10
Blood Magnesium Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Blood Pressure Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	3	0
Blood Thyroid Stimulating Hormone Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Blood Thyroid Stimulating Hormone Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	0 / 72 (0.00%)
occurrences (all)	0	4	0
Body Temperature Increased alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	3	1	0
C-Reactive Protein Increased alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Creatinine Renal Clearance Decreased alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Ejection Fraction Decreased alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram T Wave Inversion alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Eosinophil Count Increased alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Gamma-Glutamyltransferase Increased alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	2 / 73 (2.74%)	1 / 72 (1.39%)
occurrences (all)	1	10	1
Haematocrit Decreased alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Haemoglobin Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	2
International Normalised Ratio Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	3 / 72 (4.17%)
occurrences (all)	0	2	4
Neutrophil Count Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	4	0
Neutrophil Count Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Platelet Count Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Red Blood Cell Count Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Thrombin Time Prolonged			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Transaminases Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0

Urine Output Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Weight Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	7 / 72 (9.72%)
occurrences (all)	0	3	7
Weight Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
White Blood Cell Count Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contrast Media Reaction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Fall			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Head Injury			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Incisional Hernia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	2
Infusion Related Reaction			
alternative dictionary used:			

MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	4 / 72 (5.56%)
occurrences (all)	0	1	5
Post Procedural Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Post Procedural Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Procedural Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Radius Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Sunburn			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Suture Related Complication			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Wound			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Congenital Hair Disorder			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Trichomegaly			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Angina Pectoris			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Atrial Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Left Ventricular Dysfunction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Myocardial Ischaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Right Ventricular Dysfunction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Sinus Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	1 / 72 (1.39%)
occurrences (all)	0	2	1
Supraventricular Extrasystoles			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Tachycardia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Ventricular Extrasystoles			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Nervous system disorders			
Cholinergic Syndrome			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	2 / 72 (2.78%)
occurrences (all)	0	4	3
Diabetic Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Dizziness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	4
Dizziness Postural			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	1	0	1
Encephalopathy			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Epilepsy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Headache			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	1 / 72 (1.39%)
occurrences (all)	0	3	2
Hepatic Encephalopathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Hypoaesthesia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hypogeusia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Lethargy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	2 / 72 (2.78%)
occurrences (all)	0	6	3
Neuropathy Peripheral			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Neurotoxicity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0

Paraesthesia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Peripheral Motor Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Peripheral Sensory Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	0 / 72 (0.00%)
occurrences (all)	0	4	0
Polyneuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences (all)	1	1	2
Radiculitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Sciatica			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Speech Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Toxic Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Tremor			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Visual Field Defect			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Agranulocytosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	9 / 73 (12.33%)	15 / 72 (20.83%)
occurrences (all)	1	28	40
Anaemia Of Malignant Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	7
Aplastic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	6
Granulocytopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	2	1
Haemorrhagic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hypochromic Anaemia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Iron Deficiency Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	2 / 72 (2.78%)
occurrences (all)	0	5	8
Leukocytosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	3 / 72 (4.17%)
occurrences (all)	0	2	3
Leukopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	14 / 73 (19.18%)	14 / 72 (19.44%)
occurrences (all)	4	63	55
Lymphadenitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	3	0
Microcytic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	24 / 73 (32.88%)	26 / 72 (36.11%)
occurrences (all)	5	96	91

Normochromic Normocytic Anaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Splenic Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Thrombocytopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	7 / 73 (9.59%)	2 / 72 (2.78%)
occurrences (all)	1	17	3
Thrombocytosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
External Ear Inflammation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Hypoacusis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Vertigo			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Vertigo Positional			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Conjunctivitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	9 / 73 (12.33%)	4 / 72 (5.56%)
occurrences (all)	0	21	6
Dry Eye			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Erythema Of Eyelid			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Eye Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Eyelid Oedema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Eyelid Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Eyelids Pruritus			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Iritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Meibomianitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Miosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Ocular Hyperaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Ocular Icterus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Vision Blurred			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Visual Acuity Reduced			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Visual Impairment			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1

Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Abdominal Distension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	2 / 72 (2.78%)
occurrences (all)	0	3	2
Abdominal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	11 / 73 (15.07%)	14 / 72 (19.44%)
occurrences (all)	0	18	24
Abdominal Pain Lower			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Abdominal Pain Upper			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	5 / 73 (6.85%)	5 / 72 (6.94%)
occurrences (all)	0	8	5
Abdominal Tenderness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Anal Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	1	1	0
Anorectal Discomfort			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Aphthous Stomatitis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	2 / 3 (66.67%)	2 / 73 (2.74%)	4 / 72 (5.56%)
occurrences (all)	2	2	4
Ascites			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	3 / 72 (4.17%)
occurrences (all)	0	3	3
Cheilitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Colitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	7 / 73 (9.59%)	7 / 72 (9.72%)
occurrences (all)	1	14	13
Diarrhoea			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	31 / 73 (42.47%)	48 / 72 (66.67%)
occurrences (all)	15	128	197
Dry Mouth			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2
Dyspepsia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	4 / 73 (5.48%)	5 / 72 (6.94%)
occurrences (all)	0	6	6
Dysphagia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0

Enteritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2
Enterovesical Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	2	0	0
Faecal Vomiting			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Flatulence			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2
Food Poisoning			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Frequent Bowel Movements			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Gastritis Erosive			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Gastrointestinal Motility Disorder			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal Toxicity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal Reflux Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	1 / 72 (1.39%)
occurrences (all)	0	2	1
Gastrooesophageal Sphincter Insufficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Gingival Bleeding			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2
Haematochezia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Haemorrhoidal Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Haemorrhoids			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	3 / 72 (4.17%)
occurrences (all)	0	3	3
Intestinal Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0

Intestinal Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Intestinal Villi Atrophy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Lip Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Mesenteric Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Mouth Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	0 / 72 (0.00%)
occurrences (all)	0	4	0
Mucous Stools			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Nausea			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	21 / 73 (28.77%)	25 / 72 (34.72%)
occurrences (all)	2	41	62
Odynophagia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Oral Pain			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Pancreatitis Acute			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Paraesthesia Oral			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Periodontal Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	4 / 72 (5.56%)
occurrences (all)	0	2	6
Rectal Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Rectal Haemorrhage			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	3 / 72 (4.17%)
occurrences (all)	0	2	5
Rectal Tenesmus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	8 / 73 (10.96%)	18 / 72 (25.00%)
occurrences (all)	0	9	37

Subileus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Tongue Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Tooth Discolouration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Tooth Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Toothache			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	14 / 73 (19.18%)	12 / 72 (16.67%)
occurrences (all)	6	21	24
Hepatobiliary disorders			
Biliary Colic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Cholestasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Hepatic Pain			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hepatic Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	4 / 72 (5.56%)
occurrences (all)	0	2	16
Jaundice			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	3
Skin and subcutaneous tissue disorders			
Acne			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	12 / 73 (16.44%)	7 / 72 (9.72%)
occurrences (all)	0	26	18
Alopecia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	19 / 73 (26.03%)	12 / 72 (16.67%)
occurrences (all)	2	26	19
Dermal Cyst			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	3
Dermatitis Acneiform			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	13 / 73 (17.81%)	14 / 72 (19.44%)
occurrences (all)	5	19	41
Dermatitis Allergic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	1	0	0
Dermatitis Atopic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	5
Drug Eruption			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	6	0
Dry Skin			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	9 / 73 (12.33%)	9 / 72 (12.50%)
occurrences (all)	0	14	19
Eczema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Erythema			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	2 / 73 (2.74%)	5 / 72 (6.94%)
occurrences (all)	1	2	14
Exfoliative Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1

Hyperhidrosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Hyperkeratosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Hypertrichosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences (all)	0	1	2
Ingrowing Nail			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	3	0
Intertrigo			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Nail Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	1 / 72 (1.39%)
occurrences (all)	0	2	2
Nail Toxicity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Night Sweats			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Onychoclasis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Palmar-Plantar Erythrodysaesthesia Syndrome			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	7 / 73 (9.59%)	7 / 72 (9.72%)
occurrences (all)	0	10	12
Panniculitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Penile Ulceration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Petechiae			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Pigmentation Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Prurigo			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Pruritus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	6 / 73 (8.22%)	9 / 72 (12.50%)
occurrences (all)	0	8	13
Pruritus Generalised			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2

Rash			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	3 / 3 (100.00%)	37 / 73 (50.68%)	37 / 72 (51.39%)
occurrences (all)	4	75	103
Rash Generalised			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2
Rash Maculo-Papular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Rash Papular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	3 / 72 (4.17%)
occurrences (all)	0	2	4
Rash Pruritic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Rash Vesicular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Skin Chapped			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Skin Erosion			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Skin Exfoliation			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Skin Fissures			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	9 / 73 (12.33%)	5 / 72 (6.94%)
occurrences (all)	0	12	14
Skin Irritation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	3	0
Skin Ulcer			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Subcutaneous Nodule			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Toxic Skin Eruption			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	1 / 72 (1.39%)
occurrences (all)	0	4	5
Renal and urinary disorders			
Anuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Dysuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	4 / 72 (5.56%)
occurrences (all)	0	2	5
Glycosuria			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	3	0
Haematuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	1	1	1
Leukocyturia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Oliguria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Polyuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Renal Colic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Renal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1

Urethral Obstruction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Urinary Retention			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences (all)	0	1	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	4 / 73 (5.48%)	3 / 72 (4.17%)
occurrences (all)	0	7	3
Back Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	5 / 73 (6.85%)	3 / 72 (4.17%)
occurrences (all)	0	5	5
Flank Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Groin Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Inguinal Mass			

alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Joint Swelling			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Mobility Decreased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences (all)	0	2	3
Muscle Twitching			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Muscular Weakness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Chest Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	4	0
Musculoskeletal Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Myalgia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	2 / 72 (2.78%)
occurrences (all)	0	1	2
Osteoarthritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Osteopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	0 / 72 (0.00%)
occurrences (all)	0	2	0
Soft Tissue Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Synovitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	2
Infections and infestations			
Abdominal Wall Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Abscess			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Anal Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	4 / 72 (5.56%)
occurrences (all)	0	3	5
Catheter Site Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Cellulitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Cystitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	3 / 72 (4.17%)
occurrences (all)	0	2	7
Device Related Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Escherichia Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0

Folliculitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Fungal Skin Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Furuncle			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	1 / 72 (1.39%)
occurrences (all)	0	4	1
Gastroenteritis Viral			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Gastrointestinal Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Genital Candidiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Herpes Zoster			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	3
Hordeolum			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	2 / 72 (2.78%)
occurrences (all)	0	0	2
Infected Fistula			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	2
Infected Skin Ulcer			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Influenza			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	4 / 73 (5.48%)	0 / 72 (0.00%)
occurrences (all)	0	5	0
Keratitis Herpetic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Laryngitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Localised Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Lower Respiratory Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1

Lung Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Lyme Disease			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Nail Bed Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	5 / 73 (6.85%)	2 / 72 (2.78%)
occurrences (all)	1	5	2
Oesophageal Candidiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Oral Candidiasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	2
Oral Fungal Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Oral Herpes			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Oral Infection			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Otitis Externa			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Paronychia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	11 / 73 (15.07%)	6 / 72 (8.33%)
occurrences (all)	0	25	10
Pharyngitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Pharyngotonsillitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	1	1
Postoperative Wound Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Pulpitis Dental			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Rash Pustular			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	5	1

Rhinitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 73 (0.00%)	6 / 72 (8.33%)
occurrences (all)	1	0	7
Sepsis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Severe Acute Respiratory Syndrome			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	1 / 72 (1.39%)
occurrences (all)	0	2	2
Streptococcal Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Subcutaneous Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Tinea Pedis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	6 / 73 (8.22%)	3 / 72 (4.17%)
occurrences (all)	0	7	4
Urinary Tract Infection			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 3 (33.33%)	3 / 73 (4.11%)	6 / 72 (8.33%)
occurrences (all)	1	7	8
Viral Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Viral Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Mycotic Infection			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Decreased Appetite			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	9 / 73 (12.33%)	11 / 72 (15.28%)
occurrences (all)	0	11	15
Dehydration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	2 / 73 (2.74%)	3 / 72 (4.17%)
occurrences (all)	0	2	3
Diabetes Mellitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	1 / 72 (1.39%)
occurrences (all)	0	3	1
Hypercalcaemia			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hypercholesterolaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	2 / 72 (2.78%)
occurrences (all)	0	4	5
Hyperkalaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	3 / 72 (4.17%)
occurrences (all)	0	1	4
Hypocalcaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	5 / 73 (6.85%)	11 / 72 (15.28%)
occurrences (all)	2	6	29
Hypoglycaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	4 / 73 (5.48%)	13 / 72 (18.06%)
occurrences (all)	5	4	27

Hypomagnesaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 3 (66.67%)	17 / 73 (23.29%)	23 / 72 (31.94%)
occurrences (all)	5	38	57
Hyponatraemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	3 / 73 (4.11%)	2 / 72 (2.78%)
occurrences (all)	0	4	3
Hypophosphataemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 3 (33.33%)	3 / 73 (4.11%)	1 / 72 (1.39%)
occurrences (all)	1	4	1
Hypoproteinaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	3 / 72 (4.17%)
occurrences (all)	0	0	3
Iron Deficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Malnutrition			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Plasma Protein Metabolism Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 73 (0.00%)	1 / 72 (1.39%)
occurrences (all)	0	0	1
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 73 (1.37%)	0 / 72 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	EMD 525797 1000 mg + SoC		
Total subjects affected by non-serious			

adverse events			
subjects affected / exposed	68 / 69 (98.55%)		
Vascular disorders			
Aortic Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Circulatory Collapse			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	3		
Flushing			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Haematoma			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Hypertension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	3 / 69 (4.35%)		
occurrences (all)	3		
Hypotension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	5 / 69 (7.25%)		
occurrences (all)	6		
Orthostatic Hypotension			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Pallor			

alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Peripheral Ischaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Phlebitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Thrombophlebitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Venous Insufficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Venous Thrombosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	20 / 69 (28.99%)		
occurrences (all)	66		
Catheter Site Erythema			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Catheter Site Rash				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Chest Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Chills				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	4			
Extravasation				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Fatigue				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	17 / 69 (24.64%)			
occurrences (all)	33			
Feeling Cold				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
General Physical Health Deterioration				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Impaired Healing				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			

Influenza Like Illness				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Injection Site Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Localised Oedema				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Malaise				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Mucosal Inflammation				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Non-Cardiac Chest Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Oedema Peripheral				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	5			
Performance Status Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Pyrexia				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	8 / 69 (11.59%)		
occurrences (all)	19		
Secretion Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Xerosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	2		
Immune system disorders			
Contrast Media Allergy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Drug Hypersensitivity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Hypersensitivity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Balanitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Breast Mass			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Breast Pain			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Haematospermia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Pelvic Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Vulvovaginal Pruritus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Asthmatic Crisis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Bronchial Secretion Retention			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Cough			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	3 / 69 (4.35%)		
occurrences (all)	3		
Dysphonia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	2		
Dyspnoea			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Dyspnoea Exertional				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Epistaxis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	7 / 69 (10.14%)			
occurrences (all)	8			
Haemoptysis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Hiccups				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Hypoxia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Nasal Congestion				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Nasal Dryness				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Obstructive Airways Disorder				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			

Oropharyngeal Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	5 / 69 (7.25%)			
occurrences (all)	6			
Productive Cough				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Pulmonary Embolism				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Pulmonary Toxicity				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Respiratory Disorder				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Rhinitis Allergic				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Rhinorrhoea				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Sputum Discoloured				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Throat Irritation				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Agitation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Anxiety			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Confusional State			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Decreased Interest			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Depressed Mood			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	3 / 69 (4.35%)		
occurrences (all)	3		
Depression			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Depressive Symptom			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Emotional Disorder			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Insomnia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	4 / 69 (5.80%)		
occurrences (all)	6		
Investigations			
Activated Partial Thromboplastin Time			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Activated Partial Thromboplastin Time Prolonged			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	3 / 69 (4.35%)		
occurrences (all)	5		
Aspartate Aminotransferase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	4 / 69 (5.80%)		
occurrences (all)	7		
Blood Alkaline Phosphatase Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	6 / 69 (8.70%)		
occurrences (all)	10		
Blood Bilirubin Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	4		
Blood Glucose Increased			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	12			
Blood Iron Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Blood Lactate Dehydrogenase Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Blood Magnesium Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Blood Pressure Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Blood Thyroid Stimulating Hormone Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Blood Thyroid Stimulating Hormone Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Body Temperature Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
C-Reactive Protein Increased				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Creatinine Renal Clearance Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Ejection Fraction Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Electrocardiogram T Wave Inversion				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Eosinophil Count Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Gamma-Glutamyltransferase Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	6			
Haematocrit Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Haemoglobin Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
International Normalised Ratio Increased				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Neutrophil Count Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	6			
Neutrophil Count Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Platelet Count Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Red Blood Cell Count Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Thrombin Time Prolonged				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Transaminases Increased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Urine Output Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Weight Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	10 / 69 (14.49%)			
occurrences (all)	12			

Weight Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
White Blood Cell Count Increased			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contrast Media Reaction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Fall			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	2		
Head Injury			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Incisional Hernia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Infusion Related Reaction			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Post Procedural Discharge			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	2		
Post Procedural Haemorrhage			
alternative dictionary used:			

MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Procedural Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Radius Fracture			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Sunburn			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Suture Related Complication			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Wound			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Congenital Hair Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Trichomegaly			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Cardiac disorders			

Angina Pectoris				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Atrial Tachycardia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Left Ventricular Dysfunction				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Myocardial Ischaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Right Ventricular Dysfunction				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Sinus Tachycardia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Supraventricular Extrasystoles				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Tachycardia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Ventricular Extrasystoles				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Cholinergic Syndrome			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	3		
Diabetic Neuropathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Dizziness			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Dizziness Postural			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Dysgeusia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	8 / 69 (11.59%)		
occurrences (all)	8		
Encephalopathy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Epilepsy			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Headache			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	3			
Hepatic Encephalopathy				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Hypoaesthesia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Hypogeusia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Lethargy				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	4			
Neuropathy Peripheral				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Neurotoxicity				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Paraesthesia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Peripheral Motor Neuropathy				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			

Peripheral Sensory Neuropathy alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 2 / 69 (2.90%) 2			
Polyneuropathy alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 1 / 69 (1.45%) 1			
Radiculitis alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 1 / 69 (1.45%) 3			
Sciatica alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 0 / 69 (0.00%) 0			
Speech Disorder alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 0 / 69 (0.00%) 0			
Toxic Neuropathy alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 1 / 69 (1.45%) 1			
Tremor alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 1 / 69 (1.45%) 1			
Visual Field Defect alternative dictionary used: MedDRA 15.0 subjects affected / exposed occurrences (all)	 0 / 69 (0.00%) 0			
Blood and lymphatic system disorders				

Agranulocytosis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	18 / 69 (26.09%)			
occurrences (all)	33			
Anaemia Of Malignant Disease				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Aplastic Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	3			
Granulocytopenia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Haemorrhagic Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Hypochromic Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Iron Deficiency Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	5			
Leukocytosis				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	4 / 69 (5.80%)			
occurrences (all)	5			
Leukopenia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	16 / 69 (23.19%)			
occurrences (all)	70			
Lymphadenitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Lymphadenopathy				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Lymphopenia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Microcytic Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Neutropenia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	26 / 69 (37.68%)			
occurrences (all)	85			
Normochromic Normocytic Anaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	3			
Splenic Vein Thrombosis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			

Thrombocytopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	3 / 69 (4.35%)		
occurrences (all)	4		
Thrombocytosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
External Ear Inflammation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Hypoacusis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Tinnitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Vertigo			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Vertigo Positional			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	2		
Conjunctivitis			

alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	8 / 69 (11.59%)			
occurrences (all)	14			
Dry Eye				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Erythema Of Eyelid				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Eye Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Eyelid Oedema				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Eyelid Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Eyelids Pruritus				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Iritis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Meibomianitis				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Miosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Ocular Hyperaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Ocular Icterus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Vision Blurred			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Visual Acuity Reduced			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Visual Impairment			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	2		
Abdominal Distension			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Abdominal Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	18 / 69 (26.09%)			
occurrences (all)	24			
Abdominal Pain Lower				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Abdominal Pain Upper				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	6 / 69 (8.70%)			
occurrences (all)	7			
Abdominal Tenderness				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Anal Haemorrhage				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Anorectal Discomfort				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Aphthous Stomatitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	9 / 69 (13.04%)			
occurrences (all)	16			
Ascites				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			

Cheilitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Colitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Constipation				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	15 / 69 (21.74%)			
occurrences (all)	22			
Diarrhoea				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	45 / 69 (65.22%)			
occurrences (all)	209			
Dry Mouth				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Dyspepsia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Dysphagia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Enteritis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Enterovesical Fistula				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Faecal Vomiting				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Flatulence				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	7 / 69 (10.14%)			
occurrences (all)	8			
Food Poisoning				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Frequent Bowel Movements				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Gastritis Erosive				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Gastrointestinal Disorder				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	3			
Gastrointestinal Motility Disorder				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Gastrointestinal Toxicity				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			

Gastrooesophageal Reflux Disease				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Gastrooesophageal Sphincter Insufficiency				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Gingival Bleeding				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Haematochezia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Haemorrhoidal Haemorrhage				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Haemorrhoids				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Intestinal Fistula				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Intestinal Haemorrhage				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Intestinal Villi Atrophy				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Lip Ulceration				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Mesenteric Vein Thrombosis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Mouth Ulceration				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Mucous Stools				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Nausea				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	25 / 69 (36.23%)			
occurrences (all)	59			
Odynophagia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Oral Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Pancreatitis Acute				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			

Paraesthesia Oral				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Periodontal Disease				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Proctalgia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	3			
Rectal Discharge				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Rectal Haemorrhage				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Rectal Tenesmus				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Stomatitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	21 / 69 (30.43%)			
occurrences (all)	35			
Subileus				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Tongue Ulceration				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Tooth Discolouration			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Tooth Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Toothache			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Vomiting			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	17 / 69 (24.64%)		
occurrences (all)	30		
Hepatobiliary disorders			
Biliary Colic			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Cholestasis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Hepatic Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Hepatic Vein Thrombosis			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Hepatomegaly				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Hyperbilirubinaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	4			
Jaundice				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Skin and subcutaneous tissue disorders				
Acne				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	12 / 69 (17.39%)			
occurrences (all)	33			
Alopecia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	15 / 69 (21.74%)			
occurrences (all)	26			
Dermal Cyst				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Dermatitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Dermatitis Acneiform				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	18 / 69 (26.09%)			
occurrences (all)	42			
Dermatitis Allergic				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Dermatitis Atopic				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Drug Eruption				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	4 / 69 (5.80%)			
occurrences (all)	5			
Dry Skin				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	11 / 69 (15.94%)			
occurrences (all)	16			
Eczema				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	4			
Erythema				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	4			
Exfoliative Rash				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Hyperhidrosis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			

Hyperkeratosis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Hypertrichosis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	4			
Ingrowing Nail				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Intertrigo				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Nail Disorder				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Nail Toxicity				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	4			
Night Sweats				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Onychoclasis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Palmar-Plantar Erythrodysaesthesia Syndrome				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	7 / 69 (10.14%)			
occurrences (all)	16			
Panniculitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Penile Ulceration				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Petechiae				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Pigmentation Disorder				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Prurigo				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Pruritus				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	10 / 69 (14.49%)			
occurrences (all)	15			
Pruritus Generalised				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Rash				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	28 / 69 (40.58%)			
occurrences (all)	76			

Rash Generalised				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Rash Maculo-Papular				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	4			
Rash Papular				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	6			
Rash Pruritic				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	6			
Rash Vesicular				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Skin Chapped				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Skin Erosion				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Skin Exfoliation				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Skin Fissures				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	5 / 69 (7.25%)		
occurrences (all)	8		
Skin Irritation			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Skin Ulcer			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	2		
Subcutaneous Nodule			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Toxic Skin Eruption			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	5		
Renal and urinary disorders			
Anuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Dysuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	3		
Glycosuria			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Haematuria			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	3			
Leukocyturia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Nephrolithiasis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Oliguria				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Polyuria				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Proteinuria				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	5			
Renal Colic				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Renal Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Urethral Obstruction				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			

Urinary Retention			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Endocrine disorders			
Hyperthyroidism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Hypothyroidism			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	2 / 69 (2.90%)		
occurrences (all)	2		
Back Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	9 / 69 (13.04%)		
occurrences (all)	10		
Flank Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Groin Pain			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Inguinal Mass			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Joint Swelling			

alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Mobility Decreased				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Muscle Spasms				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	4 / 69 (5.80%)			
occurrences (all)	5			
Muscle Twitching				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Muscular Weakness				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Musculoskeletal Chest Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Musculoskeletal Pain				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Myalgia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Osteoarthritis				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Osteopenia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Osteoporosis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Pain In Extremity			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	4 / 69 (5.80%)		
occurrences (all)	8		
Soft Tissue Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Synovitis			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abdominal Wall Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Abscess			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences (all)	1		
Anal Abscess			
alternative dictionary used: MedDRA 15.0			

subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Bronchitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Catheter Site Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Cellulitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	3			
Cystitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	4			
Device Related Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Escherichia Urinary Tract Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Eye Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Folliculitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			

Fungal Skin Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Furuncle				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Gastroenteritis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Gastroenteritis Viral				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Gastrointestinal Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Genital Candidiasis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Herpes Zoster				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Hordeolum				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Infected Fistula				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Infected Skin Ulcer				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	2			
Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Influenza				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Keratitis Herpetic				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Laryngitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Localised Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Lower Respiratory Tract Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Lung Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			

Lyme Disease				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Nail Bed Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	4 / 69 (5.80%)			
occurrences (all)	4			
Oesophageal Candidiasis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Oral Candidiasis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	5 / 69 (7.25%)			
occurrences (all)	5			
Oral Fungal Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	4			
Oral Herpes				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	3			
Oral Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Otitis Externa				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Paronychia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	5 / 69 (7.25%)			
occurrences (all)	9			
Pharyngitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Pharyngotonsillitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Pneumonia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Postoperative Wound Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Pulpitis Dental				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Rash Pustular				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Rhinitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	4			

Sepsis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Severe Acute Respiratory Syndrome				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Streptococcal Urinary Tract Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Subcutaneous Abscess				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Tinea Pedis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Tonsillitis				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Upper Respiratory Tract Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	4 / 69 (5.80%)			
occurrences (all)	4			
Urinary Tract Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	6 / 69 (8.70%)			
occurrences (all)	7			
Viral Infection				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	3			
Viral Upper Respiratory Tract Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Vulvovaginal Mycotic Infection				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Metabolism and nutrition disorders				
Cachexia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Decreased Appetite				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	20 / 69 (28.99%)			
occurrences (all)	36			
Dehydration				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	3 / 69 (4.35%)			
occurrences (all)	3			
Diabetes Mellitus				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Hypercalcaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Hypercholesterolaemia				
alternative dictionary used: MedDRA 15.0				

subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Hyperglycaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	5			
Hyperkalaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Hypermagnesaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	1 / 69 (1.45%)			
occurrences (all)	1			
Hypoalbuminaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	2 / 69 (2.90%)			
occurrences (all)	2			
Hypocalcaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	8 / 69 (11.59%)			
occurrences (all)	12			
Hypoglycaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	0 / 69 (0.00%)			
occurrences (all)	0			
Hypokalaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	15 / 69 (21.74%)			
occurrences (all)	27			
Hypomagnesaemia				
alternative dictionary used: MedDRA 15.0				
subjects affected / exposed	14 / 69 (20.29%)			
occurrences (all)	40			

Hyponatraemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	3 / 69 (4.35%)		
occurrences (all)	4		
Hypophosphataemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	9 / 69 (13.04%)		
occurrences (all)	19		
Hypoproteinaemia			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Iron Deficiency			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Malnutrition			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Plasma Protein Metabolism Disorder			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 15.0			
subjects affected / exposed	0 / 69 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 July 2009	Following changes were made: - Trial protocol substantially and re-submitted to the competent authorities and ethics committees after completion of the Safety Part to provide transparency on all safety findings during the Safety Part. - Added recommendation for more frequent monitoring of blood values if hepatic impairment occurred during the trial (based on recommended monitoring schedule from the irinotecan summary of product characteristics in subjects with impaired liver function). - Allowed for the safety assessment of subjects withdrawn due to toxicities that were excluded from the DLT definition as part of the consideration to dose-escalate by the safety monitoring committee (SMC). - Included a recommendation to avoid concomitant administration of inhibitors/inducers of CYP4503A4, as these could influence irinotecan metabolism.
10 February 2011	- Defined the doses for the Randomized Part as 500 and 1000 mg abituzumab. - Increased the number of trial sites from 55 to 70; added Israel as an extra country. - Increased the expected trial duration; the trial would end when 2/3 of the subjects of the Randomized Part experienced death and all subjects stopped treatment. - Changed the frequency of collection of hematology, biochemistry, and coagulation profiles during the Randomization Part. - Changed the details regarding action to be taken with trial drug in the event of an AE, and clarified the AE and SAE reporting period.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported