



## Clinical trial results:

**A one-year, open-label, single arm, multi-center trial evaluating the efficacy and safety of oral ICL670 (20 mg/kg/day) in patients diagnosed with transfusion-dependent iron overload**

**Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.nov> for complete trial results.**

## Summary

EudraCT number	2004-003953-16
Trial protocol	GB ES IT DK BE DE NO AT
Global end of trial date	19 July 2010

## Results information

Result version number	v1 (current)
This version publication date	06 July 2018
First version publication date	06 July 2018

## Trial information

### Trial identification

Sponsor protocol code	CICL670A2409 (core and extension)
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### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00171821
WHO universal trial number (UTN)	-

Notes:

## Sponsors

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

Notes:

## Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001103-PIP01-10
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?	Yes
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Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 July 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 July 2010
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate if fixed starting doses of deferasirox, based on transfusion history and subsequent dose titration can provide clinically acceptable chelation, as measured by serum ferritin, in the subjects with transfusional hemosiderosis and abnormal serum ferritin.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed. Rescue medication was allowed during the course of the study as per the discretion of duty physician.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 April 2005
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 83
Country: Number of subjects enrolled	China: 127
Country: Number of subjects enrolled	Egypt: 161
Country: Number of subjects enrolled	France: 153
Country: Number of subjects enrolled	Greece: 74
Country: Number of subjects enrolled	Hong Kong: 54
Country: Number of subjects enrolled	Israel: 25
Country: Number of subjects enrolled	Lebanon: 34
Country: Number of subjects enrolled	Malaysia: 129
Country: Number of subjects enrolled	Netherlands: 17
Country: Number of subjects enrolled	South Africa: 9
Country: Number of subjects enrolled	Korea, Republic of: 88
Country: Number of subjects enrolled	Switzerland: 14
Country: Number of subjects enrolled	Taiwan: 79

Country: Number of subjects enrolled	Thailand: 156
Country: Number of subjects enrolled	Turkey: 52
Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	United Kingdom: 109
Country: Number of subjects enrolled	Austria: 15
Country: Number of subjects enrolled	Belgium: 24
Country: Number of subjects enrolled	Denmark: 21
Country: Number of subjects enrolled	Germany: 93
Country: Number of subjects enrolled	Italy: 205
Worldwide total number of subjects	1744
EEA total number of subjects	733

Notes:

<b>Subjects enrolled per age group</b>	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	384
Adolescents (12-17 years)	281
Adults (18-64 years)	822
From 65 to 84 years	248
85 years and over	9

## Subject disposition

### Recruitment

Recruitment details:

The study was conducted at 136 centres in 23 countries.

### Pre-assignment

Screening details:

A total of 1744 subjects were enrolled in the study.

### Period 1

Period 1 title	Core study
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

As the study was an open-label study, this section was not applicable.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Deferasirox (thalassemic subjects) - Core Study

Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 millilitres (mL)/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

<b>Arm title</b>	Deferasirox (myelodysplastic syndrome subjects) - Core Study
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Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

<b>Arm title</b>	Deferasirox (sickle cell disease subjects) - Core Study
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Arm description:

Deferasirox was administered to the subjects suffered with sickle cell disease as per the frequency of blood transfusions history. Subjects treated with the initial dose of either 20 mg/kg/day (for the subjects with frequency of blood transfusions about 2 to 4 units/month or 7 to 14 mL/kg/month of packed RBC)

or 30 mg/kg/day (for the subjects with more frequency of blood transfusions) or 10 mg/kg/day (for the subjects with less frequency of blood transfusions).

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

<b>Arm title</b>	Deferasirox (rare anemia subjects) - Core Study
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Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

<b>Arm title</b>	Deferasirox (aplastic anemia subjects)- Core Study
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Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

<b>Arm title</b>	Deferasirox (malignant disease subjects) - Core Study
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Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

<b>Arm title</b>	Deferasirox (other disease subjects) - Core Study
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Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

Number of subjects in period 1	Deferasirox (thalassemic subjects) - Core Study	Deferasirox (myelodysplastic syndrome subjects) - Core Study	Deferasirox (sickle cell disease subjects) - Core Study
Started	1115	341	80
Completed	1010	175	63
Not completed	105	166	17
Others	42	46	10
Adverse event, non-fatal	39	78	2
Protocol violation	5	4	3
Death	4	26	-
Administrative reasons	2	6	2
Lack of efficacy	13	6	-

Number of subjects in period 1	Deferasirox (rare anemia subjects) - Core Study	Deferasirox (aplastic anemia subjects)- Core Study	Deferasirox (malignant disease subjects) - Core Study
Started	43	116	41
Completed	30	88	16
Not completed	13	28	25
Others	1	10	5
Adverse event, non-fatal	8	13	12
Protocol violation	1	-	2
Death	2	5	5
Administrative reasons	-	-	1
Lack of efficacy	1	-	-

Number of subjects in period 1	Deferasirox (other disease subjects) - Core Study
Started	8
Completed	7
Not completed	1

Others	-
Adverse event, non-fatal	1
Protocol violation	-
Death	-
Administrative reasons	-
Lack of efficacy	-

## Period 2

Period 2 title	Extension study
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

As the study was an open-label study, this section was not applicable.

## Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Deferasirox (thalassemic subjects) - Extension study

Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

<b>Arm title</b>	Deferasirox (myelodysplastic syndrome)- Extension study
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Arm description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

<b>Arm title</b>	Deferasirox (sickle cell disease subjects) - Extension study
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**Arm description:**

Deferasirox was administered to the subjects suffered with sickle cell disease as per the frequency of blood transfusions history. Subjects treated with the initial dose of either 20 mg/kg/day (for the subjects with frequency of blood transfusions about 2 to 4 units/month or 7 to 14 mL/kg/month of packed RBC) or 30 mg/kg/day (for the subjects with more frequency of blood transfusions) or 10 mg/kg/day (for the subjects with less frequency of blood transfusions).

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

**Dosage and administration details:**

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

<b>Arm title</b>	Deferasirox (rare anemia subjects)- Extension study
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**Arm description:**

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

**Dosage and administration details:**

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

<b>Arm title</b>	Deferasirox (aplastic anemia subjects) - Extension study
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**Arm description:**

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

**Dosage and administration details:**

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

<b>Arm title</b>	Deferasirox (malignant disease subjects) - Extension study
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**Arm description:**

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use



Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

<b>Arm title</b>	Deferasirox (other disease subjects) - Extension study
Arm description:	
Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Arm type	Experimental
Investigational medicinal product name	Deferasirox
Investigational medicinal product code	ICL670
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

<b>Number of subjects in period 2<sup>[1]</sup></b>	Deferasirox (thalassemic subjects) - Extension study	Deferasirox (myelodysplastic syndrome)- Extension study	Deferasirox (sickle cell disease subjects) - Extension study
Started	495	45	20
Completed	454	37	17
Not completed	41	8	3
Consent withdrawn by subject	10	2	1
Adverse event, non-fatal	4	1	1
Protocol violation	1	-	-
Death	1	3	-
Abnormal test procedure result (s)	1	-	-
Unsatisfactory therapeutic effect	21	1	-
Subject's condition no longer requires study drug	-	1	-
Lost to follow-up	2	-	1
Abnormal laboratory values (s)	1	-	-

<b>Number of subjects in period 2<sup>[1]</sup></b>	Deferasirox (rare anemia subjects)- Extension study	Deferasirox (aplastic anemia subjects) - Extension study	Deferasirox (malignant disease subjects) - Extension study
Started	6	8	2
Completed	6	7	2
Not completed	0	1	0
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	-	-	-

Protocol violation	-	-	-
Death	-	-	-
Abnormal test procedure result (s)	-	-	-
Unsatisfactory therapeutic effect	-	-	-
Subject's condition no longer requires study drug	-	-	-
Lost to follow-up	-	-	-
Abnormal laboratory values (s)	-	-	-

<b>Number of subjects in period 2<sup>[1]</sup></b>	Deferasirox (other disease subjects) - Extension study
Started	2
Completed	2
Not completed	0
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Protocol violation	-
Death	-
Abnormal test procedure result (s)	-
Unsatisfactory therapeutic effect	-
Subject's condition no longer requires study drug	-
Lost to follow-up	-
Abnormal laboratory values (s)	-

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Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all patients entered the extension phase. This is the reason for the difference in numbers.

## Baseline characteristics

### Reporting groups

Reporting group title	Deferasirox (thalassemic subjects) - Core Study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 millilitres (mL)/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (myelodysplastic syndrome subjects) - Core Study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (sickle cell disease subjects) - Core Study
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Reporting group description:

Deferasirox was administered to the subjects suffered with sickle cell disease as per the frequency of blood transfusions history. Subjects treated with the initial dose of either 20 mg/kg/day (for the subjects with frequency of blood transfusions about 2 to 4 units/month or 7 to 14 mL/kg/month of packed RBC) or 30 mg/kg/day (for the subjects with more frequency of blood transfusions) or 10 mg/kg/day (for the subjects with less frequency of blood transfusions).

Reporting group title	Deferasirox (rare anemia subjects) - Core Study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (aplastic anemia subjects)- Core Study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (malignant disease subjects) - Core Study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (other disease subjects) - Core Study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group values	Deferasirox (thalassemic subjects) - Core Study	Deferasirox (myelodysplastic syndrome subjects) - Core Study	Deferasirox (sickle cell disease subjects) - Core Study
Number of subjects	1115	341	80
Age categorial Units: Subjects			
<6 years	132	0	2
6- <12 years	215	1	13

12- <16 years	172	0	13
16- <50 years	588	14	50
50- <65 years	6	104	2
≥ 65 years	2	222	0
Age continuous			
Units: years			
arithmetic mean	18.2	67.9	23.9
full range (min-max)	2 to 72	11 to 89	4 to 60
Gender categorical			
Units: Subjects			
Female	577	137	41
Male	538	204	39

<b>Reporting group values</b>	Deferasirox (rare anemia subjects) - Core Study	Deferasirox (aplastic anemia subjects)- Core Study	Deferasirox (malignant disease subjects) - Core Study
Number of subjects	43	116	41
Age categorical			
Units: Subjects			
<6 years	4	4	1
6- <12 years	2	7	0
12- <16 years	1	5	1
16- <50 years	24	82	11
50- <65 years	3	10	12
≥ 65 years	9	8	16
Age continuous			
Units: years			
arithmetic mean	39.5	33.3	55.5
full range (min-max)	2 to 82	2 to 79	5 to 83
Gender categorical			
Units: Subjects			
Female	23	49	13
Male	20	67	28

<b>Reporting group values</b>	Deferasirox (other disease subjects) - Core Study	Total	
Number of subjects	8	1744	
Age categorical			
Units: Subjects			
<6 years	2	145	
6- <12 years	1	239	
12- <16 years	1	193	
16- <50 years	4	773	
50- <65 years	0	137	
≥ 65 years	0	257	
Age continuous			
Units: years			
arithmetic mean	23.8		
full range (min-max)	4 to 49	-	

Gender categorical			
Units: Subjects			
Female	3	843	
Male	5	901	

## End points

### End points reporting groups

Reporting group title	Deferasirox (thalassemic subjects) - Core Study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 millilitres (mL)/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Reporting group title	Deferasirox (myelodysplastic syndrome subjects) - Core Study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Reporting group title	Deferasirox (sickle cell disease subjects) - Core Study
Reporting group description: Deferasirox was administered to the subjects suffered with sickle cell disease as per the frequency of blood transfusions history. Subjects treated with the initial dose of either 20 mg/kg/day (for the subjects with frequency of blood transfusions about 2 to 4 units/month or 7 to 14 mL/kg/month of packed RBC) or 30 mg/kg/day (for the subjects with more frequency of blood transfusions) or 10 mg/kg/day (for the subjects with less frequency of blood transfusions).	
Reporting group title	Deferasirox (rare anemia subjects) - Core Study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Reporting group title	Deferasirox (aplastic anemia subjects)- Core Study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Reporting group title	Deferasirox (malignant disease subjects) - Core Study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Reporting group title	Deferasirox (other disease subjects) - Core Study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Reporting group title	Deferasirox (thalassemic subjects) - Extension study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	
Reporting group title	Deferasirox (myelodysplastic syndrome)- Extension study
Reporting group description: Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.	

Reporting group title	Deferasirox (sickle cell disease subjects) - Extension study
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Reporting group description:

Deferasirox was administered to the subjects suffered with sickle cell disease as per the frequency of blood transfusions history. Subjects treated with the initial dose of either 20 mg/kg/day (for the subjects with frequency of blood transfusions about 2 to 4 units/month or 7 to 14 mL/kg/month of packed RBC) or 30 mg/kg/day (for the subjects with more frequency of blood transfusions) or 10 mg/kg/day (for the subjects with less frequency of blood transfusions).

Reporting group title	Deferasirox (rare anemia subjects)- Extension study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (aplastic anemia subjects) - Extension study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (malignant disease subjects) - Extension study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (other disease subjects) - Extension study
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Subject analysis set title	Baseline Liver iron concentration (LIC) < 7 mg Fe/g dry weight
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 52 weeks.

Subject analysis set title	Baseline LIC greater than or equal ( $\geq$ ) 7 Fe/g dw
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

Subject analysis set title	Baseline LIC < 7 mg Fe/g dw
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Deferasirox 10 mg/kg/day or 20 mg/kg/day or 30 mg/kg/day was administered for 18 months.

## Primary: Change from baseline in serum ferritin to Week 52

End point title	Change from baseline in serum ferritin to Week 52 <sup>[1]</sup>
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End point description:

Ferritin, an iron storage protein in the body is used to measure the iron concentration in the body. Change from baseline was calculated by using the formula = Week 52 ferritin – baseline ferritin. Negative change in serum ferritin levels indicated improvement. The analysis was performed in the full analysis set (FAS)-core phase, defined as all the subjects who successfully passed screening and started or continued to receive deferasirox in the core study. If no serum ferritin determination was available at 52 weeks for a subject, the last available value was used. The 'n' signifies those subjects evaluable for this measure at specified time points for each group, respectively. Here, 99999.9 represents not applicable data because EudraCT system is not accepting "NA" for not available/not applicable data.

End point type	Primary
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End point timeframe:

Baseline of core study, Week 52

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 primary outcome measure.

End point values	Deferasirox (thalassemic subjects) - Core Study	Deferasirox (myelodysplastic syndrome subjects) - Core Study	Deferasirox (sickle cell disease subjects) - Core Study	Deferasirox (rare anemia subjects) - Core Study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1115	341	80 <sup>[2]</sup>	43 <sup>[3]</sup>
Units: nanograms/millilitres (ng/mL)				
median (full range (min-max))				
< 20 mg/kg/day (n=231,183,39,25,75,28,5)	-28.5 (-6010 to 9501)	-273.5 (-6040 to 6124)	-235 (-2315 to 2707)	-846 (-4466 to 3939)
≥ 20 to < 30 mg/kg/day (n=732,130,39,17,40,11,3)	-92.8 (-7837 to 7933)	-219 (-7125 to 14145)	-71.5 (-3728 to 2846)	-770.5 (-4522 to 7064)
≥ 30 mg/kg/day (n=141, 8, 0, 0, 0, 0, 0)	-926 (-10282 to 7680)	-638 (-1623 to 2580)	99999.9 (99999.9 to 99999.9)	99999.9 (99999.9 to 99999.9)

Notes:

[2] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

[3] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

End point values	Deferasirox (aplastic anemia subjects)- Core Study	Deferasirox (malignant disease subjects) - Core Study	Deferasirox (other disease subjects) - Core Study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116 <sup>[4]</sup>	41 <sup>[5]</sup>	8 <sup>[6]</sup>	
Units: nanograms/millilitres (ng/mL)				
median (full range (min-max))				
< 20 mg/kg/day (n=231,183,39,25,75,28,5)	-970 (-11753 to 7883)	-660.2 (-8927 to 4285)	-330 (-886 to 2004)	
≥ 20 to < 30 mg/kg/day (n=732,130,39,17,40,11,3)	-883.8 (-15704 to 13894)	-1006.7 (-3509 to 2166)	-478.5 (-2657 to 1614)	
≥ 30 mg/kg/day (n=141, 8, 0, 0, 0, 0, 0)	99999.9 (99999.9 to 99999.9)	99999.9 (99999.9 to 99999.9)	99999.9 (99999.9 to 99999.9)	

Notes:

[4] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

[5] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

[6] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

## Statistical analyses

No statistical analyses for this end point

## Primary: Change from baseline in serum ferritin to Month 18 of the extension study

End point title	Change from baseline in serum ferritin to Month 18 of the extension study <sup>[7]</sup>
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End point description:

Ferritin, an iron storage protein in the body is used to measure the iron concentration in the body. Change from baseline in the extension study was calculated by using the formula = Month 18 ferritin – baseline ferritin. Negative change in serum ferritin levels indicated improvement. The analysis was performed in the full analysis set (FAS)-extension phase, defined as all the subjects who successfully completed the core study and continued to receive deferasirox in the extension study. If no serum



ferritin determination was available at 18 months for a subject, the last available value was used. The 'n' signifies those subjects evaluable for this measure at specified time points for each group, respectively. Here, 99999.9 represents not applicable data because EudraCT system is not accepting "NA" for not available/not applicable data

End point type	Primary
End point timeframe:	
Baseline of extension study, Month 18 (end of extension study)	

Notes:

[7] - 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 primary outcome measure.

End point values	Deferasirox (thalassemic subjects) - Extension study	Deferasirox (myelodysplastic syndrome)- Extension study	Deferasirox (sickle cell disease subjects) - Extension study	Deferasirox (rare anemia subjects)- Extension study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	495	45 <sup>[8]</sup>	20 <sup>[9]</sup>	6 <sup>[10]</sup>
Units: ng/mL				
median (full range (min-max))				
7.5 to < 15 mg/kg/day (n=7, 11, 0, 0, 1, 1, 0)	-407 (-8038 to 25127.2)	-417 (-2431 to 1914)	99999.9 (-99999.9 to 99999.9)	99999.9 (-99999.9 to 99999.9)
15 to < 25 mg/kg/day (n=214, 19, 19, 5, 6, 1, 2)	-495.25 (-1055 to 402.5)	-192 (-8225 to 2349.5)	-990 (-2497.5 to 2846)	-715 (-1782 to 987.1)
25 to < 35 mg/kg/day (n=203, 14, 1, 1, 1, 0, 0)	-729 (-8699.9 to 4287.1)	-736 (-6575.5 to 1899)	-6180 (-6180 to -6180)	1999.7 (1999.7 to 1999.7)
≥ 35 mg/kg/day (n=70, 0, 0, 0, 0, 0, 0)	-2203 (-11982.1 to 6233.7)	99999.9 (-99999.9 to 99999.9)	99999.9 (-99999.9 to 99999.9)	99999.9 (-99999.9 to 99999.9)

Notes:

[8] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

[9] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

[10] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

End point values	Deferasirox (aplastic anemia subjects) - Extension study	Deferasirox (malignant disease subjects) - Extension study	Deferasirox (other disease subjects) - Extension study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8 <sup>[11]</sup>	2 <sup>[12]</sup>	2 <sup>[13]</sup>	
Units: ng/mL				
median (full range (min-max))				
7.5 to < 15 mg/kg/day (n=7, 11, 0, 0, 1, 1, 0)	-2862.1 (-2862.1 to -2862.1)	-4546.5 (-4546.5 to -4546.5)	99999.9 (-99999.9 to 99999.9)	
15 to < 25 mg/kg/day (n=214, 19, 19, 5, 6, 1, 2)	-948.25 (-3693.9 to 549.6)	-15100.5 (-15100.5 to -15100.5)	759 (-1720 to 3238)	
25 to < 35 mg/kg/day (n=203, 14, 1, 1, 1, 0, 0)	-11224.2 (-11224.2 to -11224.2)	99999.9 (-99999.9 to 99999.9)	99999.9 (-99999.9 to 99999.9)	
≥ 35 mg/kg/day (n=70, 0, 0, 0, 0, 0, 0)	99999.9 (-99999.9 to 99999.9)	99999.9 (-99999.9 to 99999.9)	99999.9 (-99999.9 to 99999.9)	

Notes:

[11] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

[12] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

[13] - 99999.9 represents not applicable data as total number of subject analysed was 0 in category (ies)

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change from baseline in Liver iron concentration (LIC) at Week 52

End point title	Absolute change from baseline in Liver iron concentration (LIC) at Week 52
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End point description:

LIC was assessed by noninvasive magnetic resonance imaging of the proton transverse relaxation rate (R2MRI). The change in serum ferritin from baseline to week 52 was analysed in the subgroup population of subjects with baseline LIC less than (<) 7 mg Fe/g dry weight (dw). Absolute change from baseline in LIC was calculated as week 52 value–baseline value. The analysis was performed in FAS-core phase population.

End point type	Secondary
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End point timeframe:

Baseline of core study, Week 52

<b>End point values</b>	Baseline Liver iron concentration (LIC) < 7 mg Fe/g dry weight			
Subject group type	Subject analysis set			
Number of subjects analysed	71			
Units: Fe/g dw				
arithmetic mean (standard deviation)	-0.02 (± 2.368)			

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change from baseline in transferrin at Week 52

End point title	Absolute change from baseline in transferrin at Week 52
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End point description:

Change from baseline was calculated by using the formula = Week 52 transferrin – baseline transferrin. The analysis was performed in FAS-core phase population. Here, "Number of subjects analysed" signifies those subjects evaluable for absolute change from baseline in transferrin at end of the study at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline of core study, Week 52

End point values	Deferasirox (thalassemic subjects) - Core Study	Deferasirox (myelodysplastic syndrome subjects) - Core Study	Deferasirox (sickle cell disease subjects) - Core Study	Deferasirox (rare anemia subjects) - Core Study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1004	169	64	30
Units: grams/litres				
arithmetic mean (standard deviation)	0.1 (± 0.21)	0.1 (± 0.21)	0.1 (± 0.2)	0.2 (± 0.29)

End point values	Deferasirox (aplastic anemia subjects)- Core Study	Deferasirox (malignant disease subjects) - Core Study	Deferasirox (other disease subjects) - Core Study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	17	7	
Units: grams/litres				
arithmetic mean (standard deviation)	0.2 (± 0.33)	0.3 (± 0.34)	0.1 (± 0.31)	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Absolute change from baseline in transferrin saturation at Week 52

End point title	Absolute change from baseline in transferrin saturation at Week 52
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End point description:

Change from baseline was calculated by using the formula = Week 52 transferrin saturation – baseline transferrin saturation. The analysis was performed in FAS-core phase population. Here, "Number of subjects analysed" signifies those subjects evaluable for absolute change from baseline in transferrin saturation at end of the study at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline of core study, Week 56

End point values	Deferasirox (thalassemic subjects) - Core Study	Deferasirox (myelodysplastic syndrome subjects) - Core Study	Deferasirox (sickle cell disease subjects) - Core Study	Deferasirox (rare anemia subjects) - Core Study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	591	37	45	17
Units: Percent saturation				

arithmetic mean (standard deviation)	10.9 (± 34.85)	-0.1 (± 21.92)	6.4 (± 23.74)	-7.6 (± 17.66)
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End point values	Deferasirox (aplastic anemia subjects)- Core Study	Deferasirox (malignant disease subjects) - Core Study	Deferasirox (other disease subjects) - Core Study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	10	4	
Units: Percent saturation				
arithmetic mean (standard deviation)	-5.8 (± 30.29)	-20.2 (± 23.4)	2.5 (± 43.3)	

### Statistical analyses

No statistical analyses for this end point

### Secondary: Absolute change from baseline in total iron at Week 52

End point title	Absolute change from baseline in total iron at Week 52
End point description:	
Absolute change from baseline in total iron during study by visit and underlying disease was measured. The analysis was performed in FAS-core phase population. Here, "Number of subjects analysed" signifies those subjects evaluable for absolute change from baseline in total iron at end of the study at specified time points for each arm, respectively.	
End point type	Secondary
End point timeframe:	
Baseline of core study, Week 52	

End point values	Deferasirox (thalassemic subjects) - Core Study	Deferasirox (myelodysplastic syndrome subjects) - Core Study	Deferasirox (sickle cell disease subjects) - Core Study	Deferasirox (rare anemia subjects) - Core Study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1004	170	59	30
Units: micromoles/litres				
arithmetic mean (standard deviation)	7.7 (± 17.32)	6.7 (± 12.66)	3.4 (± 10.23)	0.7 (± 9.62)

End point values	Deferasirox (aplastic anemia subjects)- Core Study	Deferasirox (malignant disease subjects) - Core Study	Deferasirox (other disease subjects) - Core Study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	88	16	7	
Units: micromoles/litres				

arithmetic mean (standard deviation)	1 ( $\pm$ 13.82)	-1.5 ( $\pm$ 16.58)	3.2 ( $\pm$ 9.64)	
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## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with adverse events (AEs), serious adverse events (SAEs), treatment related AEs or SAEs and deaths during core study

End point title	Number of subjects with adverse events (AEs), serious adverse events (SAEs), treatment related AEs or SAEs and deaths during core study
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End point description:

An AE was defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of study drug, whether or not related to study drug. A SAE was defined as an event which was fatal or life threatening, required or prolonged hospitalization, was significantly or permanently disabling or incapacitating, constituted a congenital anomaly or a birth defect, or encompassed any other clinically significant event that could jeopardize the subject or require medical or surgical intervention to prevent one of the aforementioned outcomes. Treatment related AEs were defined as AEs that were suspected to be related to study treatment as per investigator. The analysis was performed in the safety analysis set-core phase, defined as all the subjects who received at least one dose of deferasirox and had at least one post baseline safety assessment in the core study.

End point type	Secondary
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End point timeframe:

Baseline of core study, Week 52

End point values	Deferasirox (thalassemic subjects) - Core Study	Deferasirox (myelodysplastic syndrome subjects) - Core Study	Deferasirox (sickle cell disease subjects) - Core Study	Deferasirox (rare anemia subjects) - Core Study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1115	341	80	43
Units: Subjects				
AEs	883	327	66	42
AEs leading to discontinuation	51	108	3	9
AEs suspected to be drug related	492	226	32	30
SAEs	101	143	30	13
SAEs suspected to be drug related	11	15	2	0
Deaths	4	26	0	2

End point values	Deferasirox (aplastic anemia subjects)- Core Study	Deferasirox (malignant disease subjects) - Core Study	Deferasirox (other disease subjects) - Core Study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	41	8	

Units: Subjects				
AEs	110	41	8	
AEs leading to discontinuation	18	18	1	
AEs suspected to be drug related	64	28	5	
SAEs	26	21	2	
SAEs suspected to be drug related	0	3	0	
Deaths	5	5	0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change from baseline in Liver iron concentration (LIC) at Month 18 in the extension study

End point title	Absolute change from baseline in Liver iron concentration (LIC) at Month 18 in the extension study
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End point description:

LIC was assessed by non-invasive R2MRI. The change in serum ferritin from baseline of extension study to month 18 was analysed in the subgroup population of subjects with baseline LIC less than < 7 mg Fe/g dw and  $\geq$  7 mg Fe/g dw. Absolute change from baseline in LIC was calculated as respective time point value–baseline value. The analysis was performed in FAS-extension phase.

End point type	Secondary
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End point timeframe:

Baseline of extension study, Month 18 (end of extension study)

End point values	Baseline LIC < 7 mg Fe/g dw	Baseline LIC greater than or equal ( $\geq$ ) 7 Fe/g dw		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	9	157		
Units: Fe/g dw				
arithmetic mean (standard deviation)	-0.5 (± 2.88)	-9.8 (± 12.15)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with adverse events (AEs), serious adverse events (SAEs), AEs leading to discontinuation, treatment related AEs and deaths during extension study

End point title	Number of subjects with adverse events (AEs), serious adverse events (SAEs), AEs leading to discontinuation, treatment related AEs and deaths during extension study
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End point description:

An AE was defined as any unfavorable and unintended sign, symptom, or disease temporally associated with the use of study drug, whether or not related to study drug. A SAE was defined as an event which was fatal or life threatening, required or prolonged hospitalization, was significantly or permanently

disabling or incapacitating, constituted a congenital anomaly or a birth defect, or encompassed any other clinically significant event that could jeopardize the subject or require medical or surgical intervention to prevent one of the aforementioned outcomes. Treatment related AEs were defined as AEs that were suspected to be related to study treatment as per investigator. Death was a fatal event leading to permanent cessations of all vital functions of the body. The analysis was performed in safety set, defined as all subjects from extension period who received at least one dose of study medication during the whole treatment period and had at least one post-baseline safety assessment.

End point type	Secondary
End point timeframe:	
Baseline of core study, end of extension study (Week 156)	

End point values	Deferasirox (thalassemic subjects) - Extension study	Deferasirox (myelodysplastic syndrome)- Extension study	Deferasirox (sickle cell disease subjects) - Extension study	Deferasirox (rare anemia subjects)- Extension study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	495	45	20	6
Units: Subjects				
AEs	406	43	16	6
AEs leading to discontinuation	7	2	1	0
AEs suspected to be drug related	234	25	5	4
SAEs	51	19	7	2
Deaths	1	3	0	0

End point values	Deferasirox (aplastic anemia subjects) - Extension study	Deferasirox (malignant disease subjects) - Extension study	Deferasirox (other disease subjects) - Extension study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	2	2	
Units: Subjects				
AEs	8	2	2	
AEs leading to discontinuation	0	0	0	
AEs suspected to be drug related	4	2	0	
SAEs	1	0	0	
Deaths	0	0	0	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change from baseline in transferrin at end of the extension study

End point title	Absolute change from baseline in transferrin at end of the extension study
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End point description:

Change from baseline in the extension study was calculated by using the formula = End of the study transferrin – baseline transferrin. The analysis was performed in FAS-extension phase population. Here, "Number of subjects analysed" signifies those subjects evaluable for absolute change from baseline in transferrin at end of the study at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline of extension study, End of extension study

End point values	Deferasirox (thalassemic subjects) - Extension study	Deferasirox (myelodysplastic syndrome)- Extension study	Deferasirox (sickle cell disease subjects) - Extension study	Deferasirox (rare anemia subjects)- Extension study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	493	44	20	6
Units: grams/litres				
arithmetic mean (standard deviation)	0.14 (± 0.253)	0.08 (± 0.281)	0.19 (± 0.266)	0.16 (± 0.086)

End point values	Deferasirox (aplastic anemia subjects) - Extension study	Deferasirox (malignant disease subjects) - Extension study	Deferasirox (other disease subjects) - Extension study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	2	2	
Units: grams/litres				
arithmetic mean (standard deviation)	0.18 (± 0.42)	0.83 (± 0.035)	0 (± 0.283)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change from baseline in transferrin saturation at end of the extension study

End point title	Absolute change from baseline in transferrin saturation at end of the extension study
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End point description:

Change from baseline in the extension study was calculated by using the formula = End of the study transferrin saturation – baseline transferrin saturation. The analysis was performed in FAS-extension phase population. Here, "Number of subjects analysed" signifies those subjects evaluable for absolute change from baseline in transferrin saturation at end of the study at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline of extension study, End of extension study



End point values	Deferasirox (thalassemic subjects) - Extension study	Deferasirox (myelodysplastic syndrome)- Extension study	Deferasirox (sickle cell disease subjects) - Extension study	Deferasirox (rare anemia subjects)- Extension study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	296	11	16	5
Units: Percent saturation				
arithmetic mean (standard deviation)	10.38 (± 29.14)	5.03 (± 20.113)	-3.81 (± 20.07)	-4.2 (± 19.614)

End point values	Deferasirox (aplastic anemia subjects) - Extension study	Deferasirox (malignant disease subjects) - Extension study	Deferasirox (other disease subjects) - Extension study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	1	1	
Units: Percent saturation				
arithmetic mean (standard deviation)	-1.83 (± 15.079)	-70.5 (± 0)	-41 (± 0)	

## Statistical analyses

No statistical analyses for this end point

## Secondary: Absolute change from baseline in total iron at end of the extension study

End point title	Absolute change from baseline in total iron at end of the extension study
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End point description:

Absolute change from baseline in total iron during extension study by visit and underlying disease was measured. The analysis was performed in FAS-extension phase population. Here, "Number of subjects analysed" signifies those subjects evaluable for absolute change from baseline in total iron at end of the study at specified time points for each arm, respectively.

End point type	Secondary
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End point timeframe:

Baseline of extension study, End of the extension study

<b>End point values</b>	Deferasirox (thalassemic subjects) - Extension study	Deferasirox (myelodysplastic syndrome)- Extension study	Deferasirox (sickle cell disease subjects) - Extension study	Deferasirox (rare anemia subjects)- Extension study
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	494	44	20	6
Units: micromoles/litres				
arithmetic mean (standard deviation)	8.55 (± 16.711)	5.98 (± 13.469)	0.8 (± 7.885)	0.33 (± 9.48)

<b>End point values</b>	Deferasirox (aplastic anemia subjects) - Extension study	Deferasirox (malignant disease subjects) - Extension study	Deferasirox (other disease subjects) - Extension study	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	2	2	
Units: micromoles/litres				
arithmetic mean (standard deviation)	4.38 (± 12.34)	-16.5 (± 14.849)	42.5 (± 57.276)	

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

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

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	13
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### Reporting groups

Reporting group title	Deferasirox (thalassemic subjects)
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 millilitres (mL)/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day.

Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (myelodysplastic syndrome subjects)
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (sickle cell disease subjects)
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Reporting group description:

Deferasirox was administered to the subjects suffered with sickle cell disease as per the frequency of blood transfusions history. Subjects treated with the initial dose of either 20 mg/kg/day (for the subjects with frequency of blood transfusions about 2 to 4 units/month or 7 to 14 mL/kg/month of packed RBC) or 30 mg/kg/day (for the subjects with more frequency of blood transfusions) or 10 mg/kg/day (for the subjects with less frequency of blood transfusions).

Reporting group title	Deferasirox (rare anemia subjects)
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (aplastic anemia subjects)
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (malignant disease subjects)
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood transfusions were administered with deferasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferasirox 30 mg/kg/day.

Reporting group title	Deferasirox (other disease subjects)
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Reporting group description:

Subjects received a recommended daily dose of deferasirox of 20 mg/kg/day based on the frequency of their blood transfusions history (7-14 mL/kg/month). Subjects receiving less number of blood

<b>Serious adverse events</b>	Deferasirox (thalassemic subjects)	Deferasirox (myelodysplastic syndrome subjects)	Deferasirox (sickle cell disease subjects)
Total subjects affected by serious adverse events			
subjects affected / exposed	101 / 1115 (9.06%)	143 / 341 (41.94%)	30 / 80 (37.50%)
number of deaths (all causes)	4	26	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Acute myeloid leukaemia			
subjects affected / exposed	0 / 1115 (0.00%)	10 / 341 (2.93%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bowen's disease			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral hygroma			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 1115 (0.00%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myeloid leukaemia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroblastoma recurrent			

subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cancer			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Angiodysplasia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial rupture			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
Haemodynamic instability			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			

subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
Hypertension			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1115 (0.00%)	4 / 341 (1.17%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pallor			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 1115 (0.09%)	5 / 341 (1.47%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concomitant disease progression			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
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			
subjects affected / exposed	0 / 1115 (0.00%)	3 / 341 (0.88%)	0 / 80 (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
Euthanasia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Face oedema			



subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
General physical health deterioration			
subjects affected / exposed	0 / 1115 (0.00%)	5 / 341 (1.47%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperpyrexia			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrosis			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	3 / 80 (3.75%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 1115 (0.09%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	4 / 80 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	12 / 1115 (1.08%)	22 / 341 (6.45%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	2 / 13	2 / 23	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Disability			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy of partner			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic ovarian cyst			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst ruptured			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Priapism			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Prostatitis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Asthma			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	3 / 1115 (0.27%)	7 / 341 (2.05%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dyspnoea exertional			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
Laryngeal dyspnoea			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 1115 (0.00%)	4 / 341 (1.17%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Painful respiration			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngolaryngeal pain			

subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1115 (0.00%)	5 / 341 (1.47%)	0 / 80 (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
Pneumonitis			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Pneumothorax			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
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 congestion			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary haemorrhage			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pulmonary hypertension			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 1115 (0.00%)	4 / 341 (1.17%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tachypnoea			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyphrenia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired self-care			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Beta-N-acetyl-D-glucosaminidase increased			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blast cell count increased			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
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			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Creatinine renal clearance decreased			



subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematocrit decreased			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (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
Heart rate irregular			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular pressure increased			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial strain			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine potassium increased			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine sodium increased			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Allergic transfusion reaction			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic transfusion reaction			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod bite			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Facial bones fracture			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			

subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Femoral neck fracture			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Fractured coccyx			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic rupture			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			

subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula fracture			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skeletal injury			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Subcutaneous haematoma			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic shock			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Gastrointestinal angiodysplasia haemorrhagic			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Porphyria acute			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia			

subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	20 / 80 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 36
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 1115 (0.00%)	4 / 341 (1.17%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 1115 (0.09%)	6 / 341 (1.76%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	3 / 1115 (0.27%)	6 / 341 (1.76%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 3	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Cardiac failure acute			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			

subjects affected / exposed	3 / 1115 (0.27%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure high output			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomegaly			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular failure			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	2 / 1115 (0.18%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Cerebral haemorrhage			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Headache			



subjects affected / exposed	2 / 1115 (0.18%)	2 / 341 (0.59%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Movement disorder			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paresis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyramidal tract syndrome			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unresponsive to stimuli			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	3 / 1115 (0.27%)	9 / 341 (2.64%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 12	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia haemolytic autoimmune			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone marrow failure			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile bone marrow aplasia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
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 neutropenia			
subjects affected / exposed	0 / 1115 (0.00%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersplenism			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice acholuric			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Leukocytosis			
subjects affected / exposed	2 / 1115 (0.18%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukopenia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Neutropenia			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
Neutrophilia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reticulocytopenia			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			
subjects affected / exposed	1 / 1115 (0.09%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 1115 (0.00%)	5 / 341 (1.47%)	0 / 80 (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
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otorrhoea			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye pain			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye pruritus			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcerative keratitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
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 mass			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	5 / 1115 (0.45%)	13 / 341 (3.81%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 5	2 / 13	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 1115 (0.09%)	2 / 341 (0.59%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 1	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall disorder			

subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 1115 (0.09%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	4 / 1115 (0.36%)	8 / 341 (2.35%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 4	2 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Diverticulum			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
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			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			



subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1115 (0.00%)	4 / 341 (1.17%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haematemesis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal infarction			

subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Odynophagia			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotid gland enlargement			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
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			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Sigmoiditis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toothache			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 1115 (0.09%)	5 / 341 (1.47%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Cholecystitis acute			
subjects affected / exposed	4 / 1115 (0.36%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	2 / 1115 (0.18%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytolytic hepatitis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
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 calcification			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatosplenomegaly			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiolymphoid hyperplasia with eosinophilia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis atopic			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma gangrenosum			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (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
Rash			
subjects affected / exposed	1 / 1115 (0.09%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			

subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fanconi syndrome acquired			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Microalbuminuria			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			

subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	2 / 1115 (0.18%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	1 / 1115 (0.09%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular disorder			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			



subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 1115 (0.00%)	3 / 341 (0.88%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cyst			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
Fistula			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			

subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
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 pain			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck mass			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	2 / 80 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Rheumatoid arthritis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synostosis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 1115 (0.00%)	3 / 341 (0.88%)	0 / 80 (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
Abscess neck			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspergillosis			
subjects affected / exposed	1 / 1115 (0.09%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 1115 (0.09%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbuncle			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter related infection			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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
Catheter sepsis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 1115 (0.18%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central line infection			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial infection			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Cystitis			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (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
Enterobacter bacteraemia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile infection			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	5 / 1115 (0.45%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	3 / 80 (3.75%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Nasopharyngitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perianal abscess			



subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal abscess			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	2 / 1115 (0.18%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 1115 (0.18%)	14 / 341 (4.11%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 2	0 / 16	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia fungal			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (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
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal abscess			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	4 / 1115 (0.36%)	7 / 341 (2.05%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 4	0 / 7	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Septic shock			
subjects affected / exposed	0 / 1115 (0.00%)	5 / 341 (1.47%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic mycosis			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	3 / 1115 (0.27%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 1115 (0.09%)	6 / 341 (1.76%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	4 / 1115 (0.36%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 1115 (0.09%)	1 / 341 (0.29%)	0 / 80 (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			
Anorexia			
subjects affected / exposed	1 / 1115 (0.09%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	2 / 1115 (0.18%)	3 / 341 (0.88%)	1 / 80 (1.25%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	3 / 1115 (0.27%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			

subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic disorder			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral intake reduced			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Deferasirox (rare anemia subjects)	Deferasirox (aplastic anemia subjects)	Deferasirox (malignant disease subjects)
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 43 (30.23%)	26 / 116 (22.41%)	21 / 41 (51.22%)
number of deaths (all causes)	2	5	5
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	3 / 41 (7.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia recurrent			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder cancer recurrent			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bowen's disease			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral hygroma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myeloid leukaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroblastoma recurrent			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salivary gland cancer			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin cancer			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Angiodysplasia			



subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial rupture			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemodynamic instability			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pallor			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	1 / 43 (2.33%)	1 / 116 (0.86%)	0 / 41 (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
Concomitant disease progression			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cyst			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Euthanasia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granuloma			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperpyrexia			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multi-organ failure			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 43 (6.98%)	7 / 116 (6.03%)	3 / 41 (7.32%)
occurrences causally related to treatment / all	0 / 5	0 / 13	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Disability			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy of partner			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst ruptured			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Priapism			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchial obstruction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal dyspnoea			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infiltration			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Painful respiration			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngolaryngeal pain			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			



subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	0 / 41 (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
Pulmonary congestion			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tachypnoea			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol abuse			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradyphrenia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired self-care			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Beta-N-acetyl-D-glucosaminidase increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blast cell count increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematocrit decreased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart rate irregular			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraocular pressure increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial strain			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine potassium increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine sodium increased			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
Allergic transfusion reaction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic transfusion reaction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod bite			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical vertebral fracture			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 43 (2.33%)	1 / 116 (0.86%)	0 / 41 (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
Fractured coccyx			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 rupture			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scapula fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skeletal injury			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous haematoma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	0 / 41 (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
Thoracic vertebral fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic shock			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Gastrointestinal angiodysplasia haemorrhagic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Porphyria acute			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
Angina pectoris			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0



Atrial fibrillation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure acute			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 high output			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomegaly			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			

subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular failure			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
Aphasia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dementia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraventricular haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Movement disorder			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paresis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyramidal tract syndrome			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unresponsive to stimuli			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Blood and lymphatic system disorders</b>			
<b>Agranulocytosis</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anaemia</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Anaemia haemolytic autoimmune</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
<b>Bone marrow failure</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Coagulopathy</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Disseminated intravascular coagulation</b>			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Febrile bone marrow aplasia</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Febrile neutropenia</b>			

subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	4 / 41 (9.76%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolysis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic anaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersplenism			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 acholuric			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophilia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reticulocytopenia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenomegaly			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otorrhoea			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye pain			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye pruritus			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcerative keratitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 distension			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal mass			



subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 43 (0.00%)	3 / 116 (2.59%)	0 / 41 (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
Abdominal pain upper			
subjects affected / exposed	2 / 43 (4.65%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 43 (2.33%)	1 / 116 (0.86%)	0 / 41 (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
Diverticular perforation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 infarction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenic colitis			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (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
Odynophagia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis haemorrhagic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotid gland enlargement			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal haemorrhage			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sigmoiditis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toothache			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytolytic hepatitis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic calcification			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 cirrhosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatosplenomegaly			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatotoxicity			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiolymphoid hyperplasia with eosinophilia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis allergic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis atopic			



subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma gangrenosum			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
Anuria			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus ureteric			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fanconi syndrome acquired			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microalbuminuria			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proteinuria			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
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 tubular disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 tubular necrosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 retention			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone cyst			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint swelling			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle spasms			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			

subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck mass			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarthritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatoid arthritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synostosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
Abscess limb			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Abscess neck</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Acute tonsillitis</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Appendicitis</b>			
subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Arthritis bacterial</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Aspergillosis</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacteraemia</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacterial infection</b>			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
<b>Bacterial sepsis</b>			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbuncle			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter related infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter sepsis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Central line infection			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis infective			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridial infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter bacteraemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia infection			



subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incision site infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella bacteraemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perianal abscess			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal abscess			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	1 / 43 (2.33%)	1 / 116 (0.86%)	0 / 41 (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
Pneumonia			
subjects affected / exposed	1 / 43 (2.33%)	3 / 116 (2.59%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 fungal			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia klebsiella			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Progressive multifocal leukoencephalopathy			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 sepsis			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
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 tuberculosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal abscess			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 43 (2.33%)	3 / 116 (2.59%)	4 / 41 (9.76%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 2
Septic shock			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic mycosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth infection			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	0 / 41 (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
Hypervolaemia			

subjects affected / exposed	0 / 43 (0.00%)	1 / 116 (0.86%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral intake reduced			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Deferasirox (other disease subjects)		
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Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 8 (25.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute leukaemia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia recurrent			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder cancer recurrent			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bladder neoplasm			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bowen's disease			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral hygroma			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukaemia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoma			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelodysplastic syndrome			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelofibrosis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myeloid leukaemia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuroblastoma recurrent			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salivary gland cancer			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin cancer			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Angiodysplasia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arterial rupture			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemodynamic instability			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pallor			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Chest pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concomitant disease progression				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cyst				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disease progression				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Euthanasia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face oedema				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised oedema				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Granuloma				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperpyrexia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperthermia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multi-organ failure				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Necrosis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	2 / 8 (25.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			

Disability			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy of partner			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metrorrhagia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian cyst ruptured			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Priapism			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		



Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atelectasis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial obstruction			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cough			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Epistaxis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal dyspnoea				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infiltration				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Painful respiration				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngolaryngeal pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Productive cough				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary congestion				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary hypertension				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachypnoea			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Alcohol abuse			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alcoholism			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradyphrenia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Delirium			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Impaired self-care			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental disorder			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Beta-N-acetyl-D-glucosaminidase increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blast cell count increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Creatinine renal clearance decreased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematocrit decreased			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart rate irregular			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intraocular pressure increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial strain			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oxygen saturation decreased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urine output decreased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urine potassium increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urine sodium increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Allergic transfusion reaction			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic transfusion reaction				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthropod bite				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical vertebral fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clavicle fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extradural haematoma				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial bones fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	1 / 8 (12.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Femoral neck fracture				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur fracture				
subjects affected / exposed	1 / 8 (12.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fractured coccyx				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic rupture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaw fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar vertebral fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple injuries				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Patella fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib fracture				



subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scapula fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skeletal injury				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fractured base				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal compression fracture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic rupture				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subcutaneous haematoma				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transfusion reaction			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Traumatic shock			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Gastrointestinal angiodysplasia haemorrhagic			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Porphyria acute			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sickle cell anaemia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sickle cell anaemia with crisis			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure acute			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure high output			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomegaly				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomyopathy				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Palpitations				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Right ventricular failure				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular arrhythmia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular failure				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular tachycardia				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dementia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intercostal neuralgia			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intraventricular haemorrhage				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of consciousness				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Movement disorder				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paresis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral motor neuropathy				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral sensory neuropathy				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyramidal tract syndrome				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Somnolence				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Unresponsive to stimuli			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Agranulocytosis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia haemolytic autoimmune			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone marrow failure			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular coagulation				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile bone marrow aplasia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolysis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolytic anaemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypersplenism				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice acholuric				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukocytosis				



subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutrophilia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reticulocytopenia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenomegaly			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otorrhoea			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye pain			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye pruritus			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ulcerative keratitis			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal mass			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal wall disorder			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal fissure			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticular perforation			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulum			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysphagia			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Food poisoning				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer haemorrhage				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis haemorrhagic				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorder				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematochezia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal infarction			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic colitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Odynophagia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis haemorrhagic				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parotid gland enlargement				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritoneal haemorrhage				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal haemorrhage				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sigmoiditis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toothache				



subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytolytic hepatitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic calcification			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cirrhosis			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic failure			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatosplenomegaly			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatotoxicity			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaundice cholestatic			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver disorder			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Angioedema			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Angiolymphoid hyperplasia with eosinophilia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermatitis allergic				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermatitis atopic				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psoriasis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyoderma gangrenosum				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash maculo-papular				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Swelling face				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus ureteric			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fanconi syndrome acquired			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Microalbuminuria			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephritis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Proteinuria			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal colic			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure acute			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal tubular disorder			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal tubular necrosis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			

subjects affected / exposed	1 / 8 (12.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Back pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone cyst				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fistula				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint swelling				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle spasms				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck mass				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polyarthrititis				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rheumatoid arthritis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synostosis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess neck			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute tonsillitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspergillosis			



subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Bacteraemia</b>				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Bacterial infection</b>				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Bacterial sepsis</b>				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Bronchitis</b>				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Bronchopneumonia</b>				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Bronchopulmonary aspergillosis</b>				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Carbuncle</b>				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
<b>Catheter related infection</b>				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Catheter sepsis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Catheter site infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Central line infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholecystitis infective				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridial infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dengue fever				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterobacter bacteraemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis viral				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Incision site infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infectious mononucleosis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella bacteraemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella sepsis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver abscess				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung infection				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis externa				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic abscess				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perianal abscess				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perineal abscess				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periorbital cellulitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonsillar abscess				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia fungal				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia klebsiella				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Progressive multifocal leukoencephalopathy				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary sepsis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retroperitoneal abscess				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subcutaneous abscess				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic mycosis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth abscess				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tooth infection				



subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Typhoid fever			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound infection			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			

subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypervolaemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoalbuminaemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	0 / 8 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malnutrition				

subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic disorder			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral intake reduced			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	Deferasirox (thalassemic subjects)	Deferasirox (myelodysplastic syndrome subjects)	Deferasirox (sickle cell disease subjects)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	755 / 1115 (67.71%)	302 / 341 (88.56%)	55 / 80 (68.75%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 1115 (0.00%)	10 / 341 (2.93%)	0 / 80 (0.00%)
occurrences (all)	0	10	0
Hypertension			
subjects affected / exposed	1 / 1115 (0.09%)	14 / 341 (4.11%)	0 / 80 (0.00%)
occurrences (all)	1	15	0
Hypotension			
subjects affected / exposed	4 / 1115 (0.36%)	3 / 341 (0.88%)	1 / 80 (1.25%)
occurrences (all)	4	3	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	16 / 1115 (1.43%)	34 / 341 (9.97%)	14 / 80 (17.50%)
occurrences (all)	22	47	16
Chest pain			

subjects affected / exposed	4 / 1115 (0.36%)	4 / 341 (1.17%)	1 / 80 (1.25%)
occurrences (all)	4	6	1
Fatigue			
subjects affected / exposed	25 / 1115 (2.24%)	32 / 341 (9.38%)	2 / 80 (2.50%)
occurrences (all)	26	40	2
General physical health deterioration			
subjects affected / exposed	0 / 1115 (0.00%)	4 / 341 (1.17%)	0 / 80 (0.00%)
occurrences (all)	0	4	0
Injection site pain			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	3 / 1115 (0.27%)	19 / 341 (5.57%)	1 / 80 (1.25%)
occurrences (all)	3	21	1
Oedema peripheral			
subjects affected / exposed	26 / 1115 (2.33%)	45 / 341 (13.20%)	1 / 80 (1.25%)
occurrences (all)	32	49	1
Pain			
subjects affected / exposed	3 / 1115 (0.27%)	6 / 341 (1.76%)	3 / 80 (3.75%)
occurrences (all)	3	6	3
Pyrexia			
subjects affected / exposed	117 / 1115 (10.49%)	59 / 341 (17.30%)	7 / 80 (8.75%)
occurrences (all)	154	94	11
Secretion discharge			
subjects affected / exposed	0 / 1115 (0.00%)	1 / 341 (0.29%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	86 / 1115 (7.71%)	33 / 341 (9.68%)	7 / 80 (8.75%)
occurrences (all)	111	43	9
Dyspnoea			

subjects affected / exposed	11 / 1115 (0.99%)	24 / 341 (7.04%)	2 / 80 (2.50%)
occurrences (all)	11	28	2
Epistaxis			
subjects affected / exposed	8 / 1115 (0.72%)	10 / 341 (2.93%)	0 / 80 (0.00%)
occurrences (all)	10	12	0
Pharyngolaryngeal pain			
subjects affected / exposed	45 / 1115 (4.04%)	11 / 341 (3.23%)	0 / 80 (0.00%)
occurrences (all)	59	12	0
Productive cough			
subjects affected / exposed	10 / 1115 (0.90%)	6 / 341 (1.76%)	0 / 80 (0.00%)
occurrences (all)	10	11	0
Rhinorrhoea			
subjects affected / exposed	13 / 1115 (1.17%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences (all)	14	4	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	4 / 1115 (0.36%)	9 / 341 (2.64%)	1 / 80 (1.25%)
occurrences (all)	4	9	1
Depression			
subjects affected / exposed	4 / 1115 (0.36%)	6 / 341 (1.76%)	3 / 80 (3.75%)
occurrences (all)	4	6	3
Insomnia			
subjects affected / exposed	11 / 1115 (0.99%)	18 / 341 (5.28%)	2 / 80 (2.50%)
occurrences (all)	13	18	2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	95 / 1115 (8.52%)	5 / 341 (1.47%)	1 / 80 (1.25%)
occurrences (all)	119	5	1
Aspartate aminotransferase increased			
subjects affected / exposed	67 / 1115 (6.01%)	1 / 341 (0.29%)	1 / 80 (1.25%)
occurrences (all)	85	1	1
Blood creatinine decreased			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	68 / 1115 (6.10%)	36 / 341 (10.56%)	3 / 80 (3.75%)
occurrences (all)	115	44	3
Gallbladder palpable			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Serum ferritin increased			
subjects affected / exposed	6 / 1115 (0.54%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences (all)	8	2	0
Spleen palpable			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	4 / 1115 (0.36%)	11 / 341 (3.23%)	0 / 80 (0.00%)
occurrences (all)	4	11	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	1 / 1115 (0.09%)	0 / 341 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 1115 (0.00%)	0 / 341 (0.00%)	14 / 80 (17.50%)
occurrences (all)	0	0	23
Cardiac disorders			
Palpitations			
subjects affected / exposed	20 / 1115 (1.79%)	0 / 341 (0.00%)	2 / 80 (2.50%)
occurrences (all)	22	0	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	16 / 1115 (1.43%)	31 / 341 (9.09%)	2 / 80 (2.50%)
occurrences (all)	20	39	3
Headache			
subjects affected / exposed	89 / 1115 (7.98%)	39 / 341 (11.44%)	11 / 80 (13.75%)
occurrences (all)	116	57	13

Memory impairment subjects affected / exposed occurrences (all)	0 / 1115 (0.00%) 0	2 / 341 (0.59%) 2	1 / 80 (1.25%) 1
Muscle contractions involuntary subjects affected / exposed occurrences (all)	1 / 1115 (0.09%) 1	0 / 341 (0.00%) 0	0 / 80 (0.00%) 0
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	7 / 1115 (0.63%) 7	1 / 341 (0.29%) 1	0 / 80 (0.00%) 0
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	12 / 1115 (1.08%) 15	15 / 341 (4.40%) 16	0 / 80 (0.00%) 0
Eye disorders Eye pruritus subjects affected / exposed occurrences (all)	3 / 1115 (0.27%) 3	2 / 341 (0.59%) 2	0 / 80 (0.00%) 0
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	10 / 1115 (0.90%) 10	3 / 341 (0.88%) 3	0 / 80 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	19 / 1115 (1.70%) 21	8 / 341 (2.35%) 11	2 / 80 (2.50%) 2
Abdominal pain subjects affected / exposed occurrences (all)	100 / 1115 (8.97%) 130	48 / 341 (14.08%) 65	12 / 80 (15.00%) 13
Abdominal pain upper subjects affected / exposed occurrences (all)	54 / 1115 (4.84%) 63	44 / 341 (12.90%) 53	9 / 80 (11.25%) 13
Constipation subjects affected / exposed occurrences (all)	34 / 1115 (3.05%) 40	59 / 341 (17.30%) 73	3 / 80 (3.75%) 3
Diarrhoea subjects affected / exposed occurrences (all)	140 / 1115 (12.56%) 189	153 / 341 (44.87%) 248	18 / 80 (22.50%) 23

Dry mouth			
subjects affected / exposed	1 / 1115 (0.09%)	4 / 341 (1.17%)	1 / 80 (1.25%)
occurrences (all)	1	4	1
Dyspepsia			
subjects affected / exposed	24 / 1115 (2.15%)	17 / 341 (4.99%)	0 / 80 (0.00%)
occurrences (all)	27	20	0
Gingival bleeding			
subjects affected / exposed	1 / 1115 (0.09%)	6 / 341 (1.76%)	0 / 80 (0.00%)
occurrences (all)	1	6	0
Haemorrhoids			
subjects affected / exposed	1 / 1115 (0.09%)	6 / 341 (1.76%)	0 / 80 (0.00%)
occurrences (all)	1	6	0
Nausea			
subjects affected / exposed	80 / 1115 (7.17%)	67 / 341 (19.65%)	13 / 80 (16.25%)
occurrences (all)	103	94	17
Toothache			
subjects affected / exposed	6 / 1115 (0.54%)	6 / 341 (1.76%)	0 / 80 (0.00%)
occurrences (all)	6	6	0
Vomiting			
subjects affected / exposed	68 / 1115 (6.10%)	42 / 341 (12.32%)	6 / 80 (7.50%)
occurrences (all)	80	58	7
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	6 / 1115 (0.54%)	3 / 341 (0.88%)	0 / 80 (0.00%)
occurrences (all)	6	5	0
Petechiae			
subjects affected / exposed	1 / 1115 (0.09%)	9 / 341 (2.64%)	0 / 80 (0.00%)
occurrences (all)	1	9	0
Pruritus			
subjects affected / exposed	19 / 1115 (1.70%)	29 / 341 (8.50%)	1 / 80 (1.25%)
occurrences (all)	21	32	3
Rash			
subjects affected / exposed	160 / 1115 (14.35%)	35 / 341 (10.26%)	4 / 80 (5.00%)
occurrences (all)	179	45	9
Urticaria			



subjects affected / exposed occurrences (all)	28 / 1115 (2.51%) 37	8 / 341 (2.35%) 10	0 / 80 (0.00%) 0
Renal and urinary disorders Haematuria subjects affected / exposed occurrences (all)	1 / 1115 (0.09%) 1	3 / 341 (0.88%) 4	0 / 80 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	34 / 1115 (3.05%) 37	23 / 341 (6.74%) 24	11 / 80 (13.75%) 14
Back pain subjects affected / exposed occurrences (all)	44 / 1115 (3.95%) 53	33 / 341 (9.68%) 37	6 / 80 (7.50%) 9
Muscle spasms subjects affected / exposed occurrences (all)	10 / 1115 (0.90%) 10	23 / 341 (6.74%) 27	0 / 80 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	9 / 1115 (0.81%) 9	6 / 341 (1.76%) 6	4 / 80 (5.00%) 5
Musculoskeletal pain subjects affected / exposed occurrences (all)	8 / 1115 (0.72%) 8	5 / 341 (1.47%) 6	4 / 80 (5.00%) 5
Myalgia subjects affected / exposed occurrences (all)	22 / 1115 (1.97%) 23	15 / 341 (4.40%) 22	1 / 80 (1.25%) 1
Neck pain subjects affected / exposed occurrences (all)	7 / 1115 (0.63%) 8	2 / 341 (0.59%) 2	2 / 80 (2.50%) 2
Pain in extremity subjects affected / exposed occurrences (all)	22 / 1115 (1.97%) 24	13 / 341 (3.81%) 16	9 / 80 (11.25%) 13
Infections and infestations Acute tonsillitis subjects affected / exposed occurrences (all)	10 / 1115 (0.90%) 10	1 / 341 (0.29%) 1	1 / 80 (1.25%) 1
Bronchitis			

subjects affected / exposed	23 / 1115 (2.06%)	11 / 341 (3.23%)	4 / 80 (5.00%)
occurrences (all)	27	15	4
Gastroenteritis			
subjects affected / exposed	45 / 1115 (4.04%)	6 / 341 (1.76%)	1 / 80 (1.25%)
occurrences (all)	56	7	1
Influenza			
subjects affected / exposed	33 / 1115 (2.96%)	5 / 341 (1.47%)	4 / 80 (5.00%)
occurrences (all)	37	5	5
Lower respiratory tract infection			
subjects affected / exposed	3 / 1115 (0.27%)	6 / 341 (1.76%)	1 / 80 (1.25%)
occurrences (all)	4	12	1
Nasopharyngitis			
subjects affected / exposed	96 / 1115 (8.61%)	24 / 341 (7.04%)	6 / 80 (7.50%)
occurrences (all)	129	34	6
Pharyngitis			
subjects affected / exposed	83 / 1115 (7.44%)	5 / 341 (1.47%)	3 / 80 (3.75%)
occurrences (all)	116	5	4
Upper respiratory tract infection			
subjects affected / exposed	152 / 1115 (13.63%)	17 / 341 (4.99%)	3 / 80 (3.75%)
occurrences (all)	239	26	5
Urinary tract infection			
subjects affected / exposed	17 / 1115 (1.52%)	23 / 341 (6.74%)	3 / 80 (3.75%)
occurrences (all)	21	28	4
Viral infection			
subjects affected / exposed	17 / 1115 (1.52%)	1 / 341 (0.29%)	1 / 80 (1.25%)
occurrences (all)	18	1	1
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	11 / 1115 (0.99%)	18 / 341 (5.28%)	2 / 80 (2.50%)
occurrences (all)	11	20	2
Dehydration			
subjects affected / exposed	0 / 1115 (0.00%)	2 / 341 (0.59%)	0 / 80 (0.00%)
occurrences (all)	0	2	0

<b>Non-serious adverse events</b>	Deferasirox (rare anemia subjects)	Deferasirox (aplastic anemia subjects)	Deferasirox (malignant disease subjects)
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Total subjects affected by non-serious adverse events subjects affected / exposed	42 / 43 (97.67%)	106 / 116 (91.38%)	37 / 41 (90.24%)
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 43 (2.33%)	1 / 116 (0.86%)	4 / 41 (9.76%)
occurrences (all)	1	1	4
Hypertension			
subjects affected / exposed	0 / 43 (0.00%)	6 / 116 (5.17%)	2 / 41 (4.88%)
occurrences (all)	0	6	2
Hypotension			
subjects affected / exposed	3 / 43 (6.98%)	3 / 116 (2.59%)	1 / 41 (2.44%)
occurrences (all)	3	4	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	5 / 43 (11.63%)	8 / 116 (6.90%)	4 / 41 (9.76%)
occurrences (all)	6	8	4
Chest pain			
subjects affected / exposed	3 / 43 (6.98%)	1 / 116 (0.86%)	1 / 41 (2.44%)
occurrences (all)	4	1	1
Fatigue			
subjects affected / exposed	10 / 43 (23.26%)	9 / 116 (7.76%)	2 / 41 (4.88%)
occurrences (all)	10	11	3
General physical health deterioration			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Injection site pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	3 / 43 (6.98%)	5 / 116 (4.31%)	1 / 41 (2.44%)
occurrences (all)	3	5	2
Oedema peripheral			
subjects affected / exposed	3 / 43 (6.98%)	2 / 116 (1.72%)	4 / 41 (9.76%)
occurrences (all)	3	2	4
Pain			

subjects affected / exposed	1 / 43 (2.33%)	6 / 116 (5.17%)	0 / 41 (0.00%)
occurrences (all)	1	8	0
Pyrexia			
subjects affected / exposed	8 / 43 (18.60%)	27 / 116 (23.28%)	11 / 41 (26.83%)
occurrences (all)	12	45	13
Secretion discharge			
subjects affected / exposed	0 / 43 (0.00%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 43 (2.33%)	0 / 116 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 43 (9.30%)	13 / 116 (11.21%)	11 / 41 (26.83%)
occurrences (all)	6	19	15
Dyspnoea			
subjects affected / exposed	5 / 43 (11.63%)	6 / 116 (5.17%)	4 / 41 (9.76%)
occurrences (all)	5	9	7
Epistaxis			
subjects affected / exposed	0 / 43 (0.00%)	15 / 116 (12.93%)	3 / 41 (7.32%)
occurrences (all)	0	26	4
Pharyngolaryngeal pain			
subjects affected / exposed	3 / 43 (6.98%)	12 / 116 (10.34%)	2 / 41 (4.88%)
occurrences (all)	4	14	2
Productive cough			
subjects affected / exposed	0 / 43 (0.00%)	2 / 116 (1.72%)	3 / 41 (7.32%)
occurrences (all)	0	2	7
Rhinorrhoea			
subjects affected / exposed	0 / 43 (0.00%)	6 / 116 (5.17%)	2 / 41 (4.88%)
occurrences (all)	0	11	3
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 43 (2.33%)	2 / 116 (1.72%)	3 / 41 (7.32%)
occurrences (all)	1	3	3
Depression			

subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 3	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	6 / 116 (5.17%) 10	6 / 41 (14.63%) 8
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 9	2 / 116 (1.72%) 4	1 / 41 (2.44%) 1
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	4 / 43 (9.30%) 5	1 / 116 (0.86%) 2	1 / 41 (2.44%) 1
Blood creatinine decreased subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 7	12 / 116 (10.34%) 15	5 / 41 (12.20%) 7
Gallbladder palpable subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Serum ferritin increased subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Spleen palpable subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	1 / 116 (0.86%) 1	2 / 41 (4.88%) 2
Injury, poisoning and procedural complications			
Animal bite subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Excoriation			

subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	1 / 116 (0.86%) 1	0 / 41 (0.00%) 0
Congenital, familial and genetic disorders Sickle cell anaemia with crisis subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Cardiac disorders Palpitations subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 3	3 / 116 (2.59%) 3	0 / 41 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)  Headache subjects affected / exposed occurrences (all)  Memory impairment subjects affected / exposed occurrences (all)  Muscle contractions involuntary subjects affected / exposed occurrences (all)	5 / 43 (11.63%) 9  9 / 43 (20.93%) 9  0 / 43 (0.00%) 0  0 / 43 (0.00%) 0	14 / 116 (12.07%) 19  25 / 116 (21.55%) 40  0 / 116 (0.00%) 0  0 / 116 (0.00%) 0	3 / 41 (7.32%) 7  3 / 41 (7.32%) 3  0 / 41 (0.00%) 0  0 / 41 (0.00%) 0
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	3 / 41 (7.32%) 4
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	1 / 116 (0.86%) 1	3 / 41 (7.32%) 3
Eye disorders Eye pruritus subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Gastrointestinal disorders			

Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	6 / 116 (5.17%) 6	1 / 41 (2.44%) 1
Abdominal distension subjects affected / exposed occurrences (all)	5 / 43 (11.63%) 5	5 / 116 (4.31%) 6	0 / 41 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	8 / 43 (18.60%) 14	19 / 116 (16.38%) 28	7 / 41 (17.07%) 9
Abdominal pain upper subjects affected / exposed occurrences (all)	5 / 43 (11.63%) 5	21 / 116 (18.10%) 26	5 / 41 (12.20%) 5
Constipation subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 7	13 / 116 (11.21%) 17	4 / 41 (9.76%) 4
Diarrhoea subjects affected / exposed occurrences (all)	17 / 43 (39.53%) 26	34 / 116 (29.31%) 60	18 / 41 (43.90%) 35
Dry mouth subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	0 / 116 (0.00%) 0	2 / 41 (4.88%) 2
Dyspepsia subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2	19 / 116 (16.38%) 31	5 / 41 (12.20%) 5
Gingival bleeding subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	6 / 116 (5.17%) 16	0 / 41 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	4 / 116 (3.45%) 5	1 / 41 (2.44%) 1
Nausea subjects affected / exposed occurrences (all)	10 / 43 (23.26%) 16	38 / 116 (32.76%) 83	12 / 41 (29.27%) 20
Toothache subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	7 / 116 (6.03%) 8	1 / 41 (2.44%) 1

Vomiting subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 17	26 / 116 (22.41%) 36	6 / 41 (14.63%) 11
Skin and subcutaneous tissue disorders			
Dermatitis subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	3 / 41 (7.32%) 3
Petechiae subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 3	7 / 116 (6.03%) 13	1 / 41 (2.44%) 1
Pruritus subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 8	15 / 116 (12.93%) 18	2 / 41 (4.88%) 2
Rash subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 7	22 / 116 (18.97%) 30	2 / 41 (4.88%) 2
Urticaria subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2	9 / 116 (7.76%) 10	1 / 41 (2.44%) 1
Renal and urinary disorders			
Haematuria subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	6 / 116 (5.17%) 7	2 / 41 (4.88%) 4
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	4 / 43 (9.30%) 4	9 / 116 (7.76%) 11	4 / 41 (9.76%) 5
Back pain subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2	10 / 116 (8.62%) 11	4 / 41 (9.76%) 5
Muscle spasms subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2	6 / 116 (5.17%) 7	9 / 41 (21.95%) 9
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	2 / 41 (4.88%) 2



Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	1 / 116 (0.86%) 1	0 / 41 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 4	6 / 116 (5.17%) 6	5 / 41 (12.20%) 5
Neck pain subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	1 / 116 (0.86%) 1	0 / 41 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2	14 / 116 (12.07%) 15	1 / 41 (2.44%) 1
Infections and infestations			
Acute tonsillitis subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	0 / 116 (0.00%) 0	3 / 41 (7.32%) 5
Bronchitis subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 3	5 / 116 (4.31%) 7	2 / 41 (4.88%) 3
Gastroenteritis subjects affected / exposed occurrences (all)	5 / 43 (11.63%) 6	4 / 116 (3.45%) 4	1 / 41 (2.44%) 1
Influenza subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	1 / 116 (0.86%) 2	0 / 41 (0.00%) 0
Lower respiratory tract infection subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 4	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 6	7 / 116 (6.03%) 10	3 / 41 (7.32%) 6
Pharyngitis subjects affected / exposed occurrences (all)	1 / 43 (2.33%) 1	3 / 116 (2.59%) 3	3 / 41 (7.32%) 3
Upper respiratory tract infection			

subjects affected / exposed occurrences (all)	6 / 43 (13.95%) 8	48 / 116 (41.38%) 92	0 / 41 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 43 (4.65%) 2	3 / 116 (2.59%) 3	4 / 41 (9.76%) 6
Viral infection subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 3	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0
Metabolism and nutrition disorders Anorexia subjects affected / exposed occurrences (all)	3 / 43 (6.98%) 4	13 / 116 (11.21%) 17	3 / 41 (7.32%) 4
Dehydration subjects affected / exposed occurrences (all)	0 / 43 (0.00%) 0	0 / 116 (0.00%) 0	0 / 41 (0.00%) 0

<b>Non-serious adverse events</b>	Deferasirox (other disease subjects)		
Total subjects affected by non-serious adverse events subjects affected / exposed	8 / 8 (100.00%)		
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Hypertension subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Hypotension subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
General disorders and administration site conditions Asthenia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Chest pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		

Fatigue			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	2		
General physical health deterioration			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Injection site pain			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Oedema			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Secretion discharge			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 8 (25.00%)		
occurrences (all)	3		
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Epistaxis			

subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Pharyngolaryngeal pain			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Blood creatinine decreased			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Gallbladder palpable			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Serum ferritin increased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Spleen palpable</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Weight decreased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 8 (12.50%)</p> <p>2</p> <p>1 / 8 (12.50%)</p> <p>1</p> <p>1 / 8 (12.50%)</p> <p>1</p> <p>1 / 8 (12.50%)</p> <p>1</p>		
<p>Injury, poisoning and procedural complications</p> <p>Animal bite</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Excoriation</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 8 (12.50%)</p> <p>1</p> <p>1 / 8 (12.50%)</p> <p>1</p>		
<p>Congenital, familial and genetic disorders</p> <p>Sickle cell anaemia with crisis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 8 (0.00%)</p> <p>0</p>		
<p>Cardiac disorders</p> <p>Palpitations</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 8 (0.00%)</p> <p>0</p>		
<p>Nervous system disorders</p> <p>Dizziness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Headache</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Memory impairment</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 8 (12.50%)</p> <p>1</p> <p>2 / 8 (25.00%)</p> <p>2</p> <p>1 / 8 (12.50%)</p> <p>1</p>		

Muscle contractions involuntary subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Blood and lymphatic system disorders Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Eye disorders Eye pruritus subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Gastrointestinal disorders Abdominal discomfort subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Abdominal distension subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Abdominal pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Constipation subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Diarrhoea subjects affected / exposed occurrences (all)	4 / 8 (50.00%) 5		
Dry mouth subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		

Dyspepsia			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Gingival bleeding			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	2		
Toothache			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			

Haematuria subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 2		
Back pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Muscle spasms subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Myalgia subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Neck pain subjects affected / exposed occurrences (all)	1 / 8 (12.50%) 1		
Pain in extremity subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Infections and infestations			
Acute tonsillitis subjects affected / exposed occurrences (all)	2 / 8 (25.00%) 2		
Bronchitis subjects affected / exposed occurrences (all)	0 / 8 (0.00%) 0		
Gastroenteritis			



subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	2		
Pharyngitis			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	4 / 8 (50.00%)		
occurrences (all)	6		
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	0 / 8 (0.00%)		
occurrences (all)	0		
Dehydration			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences (all)	1		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 October 2005	Determination of LIC by R2-MRI, assessment of quality of life (QoL) and subject satisfaction were included in the secondary objective of the study.
03 May 2007	The duration of the extension study was extended to a maximum of 18 months to provide access to the study drug to subjects until commercially available.
31 July 2007	Updated safety assessment criteria for sub-analysis of subjects with LIC < 7 mg Fe/g dw.

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use <https://www.novctrd.com/CtrdWeb/home.novfor> for complete trial results.

Notes: