



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) |
|-----------------------|-----------------------------------|

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 |
|--|-----|

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:

| Subjects enrolled per age group | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 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 |
| Arm title | 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.

| | |
|------------------|--|
| Arm title | Deferasirox (myelodysplastic syndrome 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 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.

| | |
|------------------|---|
| Arm title | Deferasirox (sickle cell disease subjects) - Core Study |
|------------------|---|

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.

| | |
|------------------|---|
| Arm title | Deferasirox (rare anemia 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 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.

| | |
|------------------|--|
| Arm title | Deferasirox (aplastic anemia 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 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.

| | |
|------------------|---|
| Arm title | Deferasirox (malignant disease 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 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.

| | |
|------------------|---|
| Arm title | Deferasirox (other disease 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 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 |
| Arm title | 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.

| | |
|------------------|---|
| Arm title | Deferasirox (myelodysplastic syndrome)- 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.

| | |
|------------------|--|
| Arm title | Deferasirox (sickle cell disease subjects) - Extension study |
|------------------|--|

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.

| | |
|------------------|---|
| Arm title | Deferasirox (rare anemia subjects)- Extension study |
|------------------|---|

Arm description:

Subjects received a recommended daily dose of deferiasirox 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 deferiasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferiasirox 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.

| | |
|------------------|--|
| Arm title | Deferasirox (aplastic anemia subjects) - Extension study |
|------------------|--|

Arm description:

Subjects received a recommended daily dose of deferiasirox 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 deferiasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferiasirox 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.

| | |
|------------------|--|
| Arm title | Deferasirox (malignant disease subjects) - Extension study |
|------------------|--|

Arm description:

Subjects received a recommended daily dose of deferiasirox 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 deferiasirox; at an initial daily dose of 10 mg/kg/day. Subjects receiving more number of blood transfusions were administered with deferiasirox 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.

| | |
|---|--|
| Arm title | 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.

| Number of subjects in period 2^[1] | 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 | - | - |

| Number of subjects in period 2^[1] | 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) | - | - | - |

| Number of subjects in period 2^[1] | 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) | - |

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 |
|-----------------------|---|

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 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 |

| Reporting group values | 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 |

| Reporting group values | 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 |
|-----------------------|--|

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 |
|-----------------------|---|

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 |
|-----------------------|--|

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 |
|-----------------------|--|

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 |
|-----------------------|--|

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 |
|----------------------------|--|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

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 |
|----------------------------|---|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

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 |
|----------------------------|-----------------------------|

| | |
|---------------------------|--------------------|
| Subject analysis set type | Sub-group analysis |
|---------------------------|--------------------|

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 ^[1] |
|-----------------|--|

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 |
|----------------|---------|

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 ^[2] | 43 ^[3] |
| 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 ^[4] | 41 ^[5] | 8 ^[6] | |
| 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 ^[7] |
|-----------------|--|

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 ^[8] | 20 ^[9] | 6 ^[10] |
| 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 ^[11] | 2 ^[12] | 2 ^[13] | |
| 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 |
|-----------------|--|

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 |
|----------------|-----------|

End point timeframe:

Baseline of core study, Week 52

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | 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 |
|-----------------|---|

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 |
|----------------|-----------|

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 |
|-----------------|--|

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 |
|----------------|-----------|

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) |
|--------------------------------------|----------------|----------------|---------------|----------------|

| 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) | |
|--------------------------------------|------------------|---------------------|-------------------|--|

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 |
|-----------------|---|

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 |
|----------------|-----------|

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 |
|-----------------|--|

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 |
|----------------|-----------|

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 (\pm 2.88) | -9.8 (\pm 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 |
|-----------------|--|

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 |
|-----------------|--|

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 |
|----------------|-----------|

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 |
|-----------------|---|

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 |
|----------------|-----------|

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 |
|-----------------|---|

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 |
|----------------|-----------|

End point timeframe:

Baseline of extension study, End of the 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 | 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) |

| 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: 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 |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|----|
| Dictionary version | 13 |
|--------------------|----|

Reporting groups

| | |
|-----------------------|------------------------------------|
| Reporting group title | Deferasirox (thalassemic subjects) |
|-----------------------|------------------------------------|

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) |
|-----------------------|---|

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) |
|-----------------------|--|

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) |
|-----------------------|------------------------------------|

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) |
|-----------------------|--|

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) |
|-----------------------|--|

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) |
|-----------------------|--------------------------------------|

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

| Serious adverse events | 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 |
| Blood and lymphatic system disorders | | | |
| Agranulocytosis | | | |
| subjects affected / exposed | 0 / 43 (0.00%) | 0 / 116 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| 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 |
| Anaemia haemolytic autoimmune | | | |
| 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 |
| Bone marrow 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 |
| Coagulopathy | | | |
| 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 |
| Disseminated intravascular coagulation | | | |
| 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 |
| Febrile bone marrow aplasia | | | |
| subjects affected / exposed | 0 / 43 (0.00%) | 0 / 116 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |

| | | | |
|---|----------------|-----------------|----------------|
| 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 |
| Abscess neck | | | |
| subjects affected / exposed | 0 / 43 (0.00%) | 0 / 116 (0.00%) | 0 / 41 (0.00%) |
| 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 tonsillitis | | | |
| subjects affected / exposed | 0 / 43 (0.00%) | 0 / 116 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 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 |
| Arthritis 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 |
| Aspergillosis | | | |
| subjects affected / exposed | 0 / 43 (0.00%) | 0 / 116 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 43 (0.00%) | 0 / 116 (0.00%) | 0 / 41 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacterial 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 |
| Bacterial 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 |
| 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 |

| | | | |
|-------------------------------|--------------------------------------|--|--|
| Serious adverse events | Deferasirox (other disease subjects) | | |
|-------------------------------|--------------------------------------|--|--|

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

| | | | | |
|---|---------------|--|--|--|
| 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 %

| Non-serious adverse events | 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 |

| | | | |
|-----------------------------------|------------------------------------|--|--|
| Non-serious adverse events | Deferasirox (rare anemia subjects) | Deferasirox (aplastic anemia subjects) | Deferasirox (malignant disease subjects) |
|-----------------------------------|------------------------------------|--|--|

| | | | |
|---|------------------|--------------------|------------------|
| 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 | | | |

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

| | | | |
|---|--------------------------------------|--|--|
| Non-serious adverse events | 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 | 0 / 8 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | | |
| occurrences (all) | 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:

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: