

**Clinical trial results:**

A phase 3 multicenter, randomized, prospective, open-label trial of standard chemoimmunotherapy (FCR/BR) versus rituximab plus venetoclax (RVe) versus obinutuzumab (GA101) plus venetoclax (GVe) versus obinutuzumab plus ibrutinib plus venetoclax (GIVe) in fit patients with previously untreated chronic lymphocytic leukemia (CLL) without del(17p) or TP53 mutation.

Summary

| | |
|--------------------------|----------------------|
| EudraCT number | 2015-004936-36 |
| Trial protocol | SE DK DE AT FI BE IE |
| Global end of trial date | 29 February 2024 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v1 (current) |
| This version publication date | 12 March 2025 |
| First version publication date | 12 March 2025 |

Trial information**Trial identification**

| | |
|-----------------------|-------|
| Sponsor protocol code | CLL13 |
|-----------------------|-------|

Additional study identifiers

| | |
|------------------------------------|----------------------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02950051 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Sponsor`s number: UNI-KOELN-2751 |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | UNIVERSITY OF COLOGNE |
| Sponsor organisation address | ALBERTUS-MAGNUS-PLATZ, Cologne, Germany, 50923 |
| Public contact | Dr. med. Anna Fink, German CLL Study Group, COLOGNE UNIVERSITY HOSPITAL, KERPENER STR. 62, 50924 COLOGNE, GERMANY, +49 22147888220, anna-maria.fink@uk-koeln.de |
| Scientific contact | PROF. DR. MED. BARBARA EICHHORST, German CLL Study Group, COLOGNE UNIVERSITY HOSPITAL, KERPENER STR. 62, 50924 COLOGNE, GERMANY, +49 22147888220, barbara.eichhorst@uk-koeln.de |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 29 February 2024 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 29 February 2024 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to evaluate the efficacy of obinutuzumab (GA101) plus venetoclax (GVe) versus standard chemoimmunotherapy (BR/FCR) [concerning MRD negativity measured by flow cytometry in peripheral blood (PB) at month 15] and obinutuzumab plus ibrutinib plus venetoclax (GIVe) versus standard chemoimmunotherapy (BR/FCR) [concerning progression free survival (PFS)] in previously untreated, fit CLL patients without del(17p) or TP53 mutation.

Protection of trial subjects:

Safety measures to prevent or to manage known risks associated with CLL, such as infections or cytopenia or known adverse reactions related to any of the IMPs have been included in the protocol. Chapter 8 of the protocol included sections how to prevent and manage known side effects, including detailed instruction about premedication, modifications and treatment discontinuation. The protocol includes sections with prohibited, permitted and medication used with caution for each study medication, especially for known interactions with CYP3A4 inhibitors or inducers.

Background therapy:

For a long time, chemoimmunotherapy with fludarabine, cyclophosphamid and rituximab (FCR) for patients ≤ 65 or bendamustine plus rituximab for patients > 65 years, was considered standard first-line treatment for patients with CLL. Since several novel targeted agents such as the Btk-inhibitor ibrutinib (formerly PCI-32765), the PI3K-inhibitor CAL-101 (idelalisib) and the Bcl2-antagonist venetoclax (ABT-199, GDC-0199) have become available, the treatment landscape for CLL as faced profound changes. These new targeted agents were tested in phase-II and III-studies and showed a favorable toxicity profile and a promising efficacy with a potentially synergistic mechanism of action. The PI3K-inhibitor Idelalisib has been approved for treatment of relapsed CLL as well as frontline therapy of CLL with TP53 mut/del.

The combination of venetoclax and CD20-antibodies is approved for firstline therapy (obinutuzumab) as well as in relapsed disease (rituximab). Btk-inhibitors are approved as monotherapy in firstline treatment and relapsed disease or in combination with venetoclax or CD-20 antibodies for first line therapy.

The addition of the Btk-inhibitor ibrutinib to the venetoclax plus CD20-anitbody based combination, is expected to add significant activity by targeting a third mechanism order to drive CLL cells into apoptosis.

The aim of the CLL13 trial is to evaluate, wether the standard chemoimmunotherapy in the frontline treatment of physically fit patients in CLL can be replaced by combinations of venetoclax (and ibrutinib) with anti-CD20-antibodies, which may induce extremely long lasting remissions.

Evidence for comparator:

Chemoimmunotherapy is the standard of care in first-line treatment of CLL. In patients < 65 years, the combination of fludarabine, cyclophosphamid and rituximab is considered standard treatment, while patients >65 years usually receive bendamustine plus rituximab.

However, these conventional chemoimmunotherapies are associated with side effects caused by the rather unspecific mode of action of the chemotherapy. Therefore, there is a need for alternative, chemotherapy-free regimes. Published data support that targeted agents may show a promising response rate while having a favorable safety profile with lower rates of toxicity. All agents used in this trial have been approved in firstline treatment or in relapsed disease, as monotherapy or as combination

therapy for patients with CLL.

| | |
|---|------------------|
| Actual start date of recruitment | 13 December 2016 |
| 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 | Switzerland: 82 |
| Country: Number of subjects enrolled | Netherlands: 185 |
| Country: Number of subjects enrolled | Sweden: 53 |
| Country: Number of subjects enrolled | Austria: 36 |
| Country: Number of subjects enrolled | Belgium: 31 |
| Country: Number of subjects enrolled | Denmark: 113 |
| Country: Number of subjects enrolled | Finland: 21 |
| Country: Number of subjects enrolled | Germany: 333 |
| Country: Number of subjects enrolled | Ireland: 38 |
| Country: Number of subjects enrolled | Israel: 34 |
| Worldwide total number of subjects | 926 |
| EEA total number of subjects | 810 |

Notes:

Subjects enrolled per age group

| | |
|---|-----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 564 |
| From 65 to 84 years | 362 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Between Dec 13, 2016, and Oct 13, 2019, 1080 patients were screened for eligibility. 926 were enrolled, 154 excluded. 229 were assigned to receive chemoimmunotherapy (150 FCR, 79 BR), 237 were assigned to receive venetoclax+rituxumab, 229 were assigned to venetoclax+obinutuzumab and 231 were allocated to venetoclax+obinutuzumab+ibrutinib.

Pre-assignment

Screening details:

From 154 screening failures, 136 did not meet eligibility criteria, 4 were not included due to physician's decision and 14 due to patient's decision.

Period 1

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

Blinding implementation details:

Not applicable

Arms

| | |
|------------------------------|------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Standard chemoimmunotherapy (SCIT) |

Arm description:

The SCIT treatment consists of 6 cycles, each with a precise duration of 28 days.
Patients ≤ 65 years will receive 6 cycles of fludarabine, cyclophosphamide and rituximab (FCR).
Patients > 65 years will receive 6 cycles of bendamustine and rituximab (BR).

| | |
|--|--|
| Arm type | Active comparator |
| Investigational medicinal product name | Fludarabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive fludarabine on days 1-3 of cycle 1-6.

Cycle 1-6

Day 1 fludarabine 25mg/m² i.v.,

day 2 fludarabine 25mg/m² i.v.

day 3 fludarabine 25mg/m² i.v.

| | |
|--|--|
| Investigational medicinal product name | Cyclophosphamide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for solution for injection/infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive cyclophosphamide on days 1-3 of cycle 1-6.

Cycle 1-6

Day 1 cyclophosphamide 250mg/m² i.v.,

day 2 cyclophosphamide 250mg/m² i.v.

day 3 cyclophosphamide 250mg/m² i.v.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Rituximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive rituximab (MabThera®) intravenously before the application of chemotherapy with premedication according to clinical practice of the participating sites.

Cycle 1: 375 mg/ m² i.v.

Cycles 2-6: 500 mg/ m² i.v

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Rituximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive rituximab (MabThera®) intravenously before the application of Bendamustine with premedication according to clinical practice of the participating sites.

Cycle 1: 375 mg/ m² i.v.

Cycle 2-6: 500 mg/ m² i.v.

| | |
|--|---|
| Investigational medicinal product name | Bendamustine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder for concentrate and solution for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive bendamustine on day 1 and 2 of cycle 1-6.

Cycle 1-6

Day 1 bendamustine 90mg/m² i.v.,

day 2 bendamustine 90mg/m² i.v.

| | |
|------------------|-----------------------------|
| Arm title | Venetoclax, rituximab (RVe) |
|------------------|-----------------------------|

Arm description:

The RVe treatment consists of 12 cycles, each with a precise duration of 28 days.

| | |
|--|---------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Rituximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive rituximab (MabThera®) intravenously:

Cycle 1:

Day 1: 375 mg/ m² i.v.

Cycle 2-6:

Day 1: 500 mg/ m² i.v.

| | |
|--|--------------------|
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | ABT 199 |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |

| | |
|--------------------------|----------|
| Routes of administration | Oral use |
|--------------------------|----------|

Dosage and administration details:

Patients will receive the first dosage of venetoclax on day 22 of cycle 1. The daily intake of venetoclax starts with a weekly dose ramp-up to final dose

Venetoclax p.o.:

Cycle 1:

Days 22-28: venetoclax 20 mg (2 tabl. at 10 mg)

Cycle 2:

Days 1-7: venetoclax 50 mg (1 tabl. at 50 mg)

Days 8-14: venetoclax 100 mg (1 tabl. at 100 mg)

Days 15-21: venetoclax 200 mg (2 tabl. at 100 mg)

Days 22-28: venetoclax 400 mg (4 tabl. at 100 mg)

Cycles 3-12:

Days 1-28: venetoclax 400 mg (4 tabl. at 100 mg)

Due to the risk of adverse events, especially tumor-lysis-syndromes (TLS), the dose of venetoclax will be increased slowly every week until the final dose of 400 mg is reached (ramp-up). In order to diagnose a TLS at an early stage certain safety measures as specified in the study protocol must be followed.

On days with administration of both, venetoclax and rituximab, oral intake of venetoclax will be followed by intravenous administration of rituximab.

| | |
|------------------|--------------------------------|
| Arm title | Venetoclax, obinutuzumab (GVe) |
|------------------|--------------------------------|

Arm description:

The GVe treatment consists of 12 cycles, each with a precise duration of 28 days.

| | |
|--|--------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | ABT 199 |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Patients will receive the first dosage of venetoclax on day 22 of cycle 1. The daily intake of venetoclax starts with a weekly dose ramp-up to final dose

Venetoclax p.o.:

Cycle 1:

Days 22-28: venetoclax 20 mg (2 tabl. at 10 mg)

Cycle 2:

Days 1-7: venetoclax 50 mg (1 tabl. at 50 mg)

Days 8-14: venetoclax 100 mg (1 tabl. at 100 mg)

Days 15-21: venetoclax 200 mg (2 tabl. at 100 mg)

Days 22-28: venetoclax 400 mg (4 tabl. at 100 mg)

Cycles 3-12:

Days 1-28: venetoclax 400 mg (4 tabl. at 100 mg)

Due to the risk of adverse events, especially tumor-lysis-syndromes (TLS), the dose of venetoclax will be increased slowly every week until the final dose of 400 mg is reached (ramp-up). In order to diagnose a TLS at an early stage certain safety measures as specified in the study protocol must be followed.

On days with administration of both, venetoclax and obinutuzumab, oral intake of venetoclax will be followed by intravenous administration of obinutuzumab.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Obinutuzumab |
| Investigational medicinal product code | GA 101 |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive obinutuzumab infusions on days 1 (and 2), 8 and 15 during the first cycle, as well as on day 1 of cycles 2-6.

Obinutuzumab i.v. infusion:

Cycle 1:

Day 1: obinutuzumab 100 mg

Day 1 (or 2): obinutuzumab 900 mg

Day 8: obinutuzumab 1000 mg

Day 15: obinutuzumab 1000 mg

Cycles 2-6:

Day 1: obinutuzumab 1000 mg

The first infusion of obinutuzumab may be administered at the full dose (1000 mg) on day 1 of the first cycle if the infusion of a test-dosage of 100 mg is well tolerated by the patient. Alternatively, if the first 100mg infusion on day 1 is not tolerated well, the remaining 900 mg of the first dose should be administered on day 2.

| | |
|---|--|
| Arm title | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Arm description: The GIVe treatment consists of 12 cycles (ibrutinib might be given up to 36 cycles), each with a precise duration of 28 days. | |
| Arm type | Experimental |
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | ABT 199 |
| Other name | |
| Pharmaceutical forms | Film-coated tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Patients will receive the first dosage of venetoclax on day 22 of cycle 1. The daily intake of venetoclax starts with a weekly dose ramp-up to final dose.

Venetoclax p.o.:

Cycle 1:

Days 22-28: 20 mg (2 tabl. at 10 mg)

Cycle 2:

Days 1-7: 50 mg (1 tabl. at 50 mg)

Days 8-14: 100 mg (1 tabl. at 100 mg)

Days 15-21: 200 mg (2 tabl. at 100 mg)

Days 22-28: 400 mg (4 tabl. at 100 mg)

Cycles 3-12:

Days 1-28: 400 mg (4 tabl. at 100 mg)

Due to the risk of adverse events, especially tumor-lysis-syndromes (TLS), the dose of venetoclax will be increased slowly every week until the final dose of 400 mg is reached (ramp-up). In order to diagnose a TLS at an early stage certain safety measures as specified in the study protocol must be followed. On days with administration of more than one study drug, oral intake of ibrutinib (before breakfast) will be followed by oral intake of venetoclax (during breakfast), at least iv administration of obinutuzumab will take place if applicable.

| | |
|--|---------------------------------------|
| Investigational medicinal product name | Obinutuzumab |
| Investigational medicinal product code | GA 101 |
| Other name | |
| Pharmaceutical forms | Concentrate for solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Patients will receive obinutuzumab infusions on days 1 (and 2), 8 and 15 during the first cycle, as well as on day 1 of cycles 2-6.

obinutuzumab i.v. infusion:

Cycle 1:

Day 1: obinutuzumab 100 mg

Day 1 (or 2): obinutuzumab 900 mg

Day 8: obinutuzumab 1000 mg

Day 15: obinutuzumab 1000 mg

Cycles 2-6:

Day 1: obinutuzumab 1000 mg

| | |
|--|---------------|
| Investigational medicinal product name | Ibrutinib |
| Investigational medicinal product code | PCI-32765 |
| Other name | |
| Pharmaceutical forms | Capsule, hard |
| Routes of administration | Oral use |

Dosage and administration details:

Patients will receive ibrutinib as a daily oral dosage of 420 mg starting on cycle 1 day 1 until MRD negativity (i.e. $< 10^{-4}$) in peripheral blood and confirmed by a bone marrow aspirate or by two consecutive peripheral blood samples (cycle 9/12 or 12/15; all other patients will continue treatment) or 36 months of treatment are reached.

Ibrutinib p.o.:

Cycles 1-12:

Days 1-28: 420mg daily

Cycles 13-36:

Days 1-28: ibrutinib 420 mg daily

| Number of subjects in period 1 | Standard chemoimmunothera py (SCIT) | Venetoclax, rituximab (RVe) | Venetoclax, obinutuzumab (GVe) |
|-------------------------------------|---|--------------------------------|-----------------------------------|
| | | | |
| Started | 229 | 237 | 229 |
| Completed | 176 | 219 | 214 |
| Not completed | 53 | 18 | 15 |
| Adverse event, non-fatal | 32 | 11 | 9 |
| Death | - | 1 | 1 |
| Non-compliance | 2 | - | 1 |
| Progressive disease | 2 | 4 | 3 |
| Did not receive any study treatment | 13 | - | 1 |
| other reason | 4 | 2 | - |

| Number of subjects in period 1 | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
|-------------------------------------|--|
| Started | 231 |
| Completed | 199 |
| Not completed | 32 |
| Adverse event, non-fatal | 27 |
| Death | 2 |
| Non-compliance | - |
| Progressive disease | - |
| Did not receive any study treatment | - |
| other reason | 3 |

Baseline characteristics

Reporting groups

| | |
|---|--|
| Reporting group title | Standard chemoimmunotherapy (SCIT) |
| Reporting group description: | |
| The SCIT treatment consists of 6 cycles, each with a precise duration of 28 days. | |
| Patients ≤ 65 years will receive 6 cycles of fludarabine, cyclophosphamide and rituximab (FCR). | |
| Patients > 65 years will receive 6 cycles of bendamustine and rituximab (BR). | |
| Reporting group title | Venetoclax, rituximab (RVe) |
| Reporting group description: | |
| The RVe treatment consists of 12 cycles, each with a precise duration of 28 days. | |
| Reporting group title | Venetoclax, obinutuzumab (GVe) |
| Reporting group description: | |
| The GVe treatment consists of 12 cycles, each with a precise duration of 28 days. | |
| Reporting group title | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Reporting group description: | |
| The GIVe treatment consists of 12 cycles (ibrutinib might be given up to 36 cycles), each with a precise duration of 28 days. | |

| Reporting group values | Standard chemoimmunotherapy (SCIT) | Venetoclax, rituximab (RVe) | Venetoclax, obinutuzumab (GVe) |
|------------------------|------------------------------------|-----------------------------|--------------------------------|
| Number of subjects | 229 | 237 | 229 |
| Age categorical | | | |
| Units: Subjects | | | |
| Adults (18-64 years) | 145 | 141 | 139 |
| From 65-84 years | 84 | 96 | 90 |
| 85 years and over | 0 | 0 | 0 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 66 | 62 | 58 |
| Male | 163 | 175 | 171 |
| Country | | | |
| Units: Subjects | | | |
| Germany | 85 | 85 | 81 |
| Denmark | 25 | 31 | 25 |
| Netherlands | 43 | 47 | 49 |
| Sweden | 14 | 13 | 17 |
| Switzerland | 21 | 21 | 21 |
| Belgium | 12 | 7 | 5 |
| Austria | 8 | 9 | 11 |
| Finland | 6 | 4 | 5 |
| Ireland | 8 | 9 | 10 |
| Israel | 7 | 11 | 5 |
| Binet stage | | | |
| Units: Subjects | | | |
| Binet A | 63 | 61 | 58 |
| Binet B | 84 | 92 | 91 |
| Binet C | 82 | 84 | 80 |
| IGHV mutational status | | | |
| Units: Subjects | | | |

| | | | |
|--|-----|-----|-----|
| unmutated | 131 | 134 | 130 |
| mutated | 95 | 95 | 89 |
| not evaluable | 3 | 8 | 9 |
| missing information | 0 | 0 | 1 |
| CLL-IPI risk group Units: Subjects | | | |
| low | 36 | 39 | 32 |
| intermediate | 67 | 66 | 76 |
| high | 122 | 123 | 109 |
| very high | 0 | 0 | 0 |
| missing information | 4 | 9 | 12 |
| Complex karyotype Units: Subjects | | | |
| < 3 aberrations | 177 | 187 | 182 |
| ≥ 3 and < 5 aberrations | 30 | 34 | 25 |
| ≥ 5 aberrations | 16 | 10 | 11 |
| missing information | 6 | 6 | 11 |
| Binet stage used for stratification Units: Subjects | | | |
| Binet A | 61 | 62 | 60 |
| Binet B | 85 | 90 | 90 |
| Binet C | 83 | 85 | 79 |

| Reporting group values | Venetoclax, obinutuzmab, ibrutinib (GIVe) | Total | |
|---------------------------------------|---|-------|--|
| Number of subjects | 231 | 926 | |
| Age categorical Units: Subjects | | | |
| Adults (18-64 years) | 139 | 564 | |
| From 65-84 years | 92 | 362 | |
| 85 years and over | 0 | 0 | |
| Gender categorical Units: Subjects | | | |
| Female | 73 | 259 | |
| Male | 158 | 667 | |
| Country Units: Subjects | | | |
| Germany | 82 | 333 | |
| Denmark | 32 | 113 | |
| Netherlands | 46 | 185 | |
| Sweden | 9 | 53 | |
| Switzerland | 19 | 82 | |
| Belgium | 7 | 31 | |
| Austria | 8 | 36 | |
| Finland | 6 | 21 | |
| Ireland | 11 | 38 | |
| Israel | 11 | 34 | |
| Binet stage Units: Subjects | | | |
| Binet A | 63 | 245 | |
| Binet B | 84 | 351 | |

| | | | |
|--|-----|-----|--|
| Binet C | 84 | 330 | |
| IGHV mutational status Units: Subjects | | | |
| unmutated | 123 | 518 | |
| mutated | 101 | 380 | |
| not evaluable | 7 | 27 | |
| missing information | 0 | 1 | |
| CLL-IPI risk group Units: Subjects | | | |
| low | 36 | 143 | |
| intermediate | 85 | 294 | |
| high | 101 | 455 | |
| very high | 0 | 0 | |
| missing information | 9 | 34 | |
| Complex karyotype Units: Subjects | | | |
| < 3 aberrations | 196 | 742 | |
| ≥ 3 and < 5 aberrations | 21 | 110 | |
| ≥ 5 aberrations | 6 | 43 | |
| missing information | 8 | 31 | |
| Binet stage used for stratification Units: Subjects | | | |
| Binet A | 63 | 246 | |
| Binet B | 84 | 349 | |
| Binet C | 84 | 331 | |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | Standard chemoimmunotherapy (SCIT) |
| Reporting group description: The SCIT treatment consists of 6 cycles, each with a precise duration of 28 days. Patients ≤ 65 years will receive 6 cycles of fludarabine, cyclophosphamide and rituximab (FCR). Patients > 65 years will receive 6 cycles of bendamustine and rituximab (BR). | |
| Reporting group title | Venetoclax, rituximab (RVe) |
| Reporting group description: The RVe treatment consists of 12 cycles, each with a precise duration of 28 days. | |
| Reporting group title | Venetoclax, obinutuzumab (GVe) |
| Reporting group description: The GVe treatment consists of 12 cycles, each with a precise duration of 28 days. | |
| Reporting group title | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Reporting group description: The GIVe treatment consists of 12 cycles (ibrutinib might be given up to 36 cycles), each with a precise duration of 28 days. | |

Primary: Progression free survival (PFS) [GIVe versus SCIT]

| | |
|---|---|
| End point title | Progression free survival (PFS) [GIVe versus SCIT] ^[1] |
| End point description: One co-primary efficacy endpoint is the investigator-assessed PFS, defined as the time from randomization to the first occurrence of progression or relapse (determined using standard IWCLL guidelines [2008]), or death from any cause, whichever occurs first. For patients who have not progressed, relapsed, or died at the time of analysis, PFS will be censored on the date of the last tumor assessment. In case of initiation of subsequent anti-leukemic treatment without documented disease progression patient will be censored at last tumor assessment prior to start of subsequent therapy. If no tumor assessments were performed after the screening visit, PFS will be censored at the time of randomization + 1 day. Median PFS and the 97.5% CI will be estimated using Kaplan-Meier survival methodology, with the Kaplan-Meier survival curve presented to provide a visual description. PFS rates for 1, 2 and 3 years etc. after randomization will be reported. | |
| End point type | Primary |
| End point timeframe: Data will be collected from randomization until last visit of each study subject. | |
| Notes: | |

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The statistics for the comparisons of the other arms are reported in a separate endpoint as only the comparison between GIVE versus SCIT was considered as primary endpoint in this analysis. The other comparisons are considered as secondary endpoint and are reported as secondary endpoint accordingly.

| End point values | Standard chemoimmunotherapy (SCIT) | Venetoclax, obinutuzumab, ibrutinib (GIVe) | | |
|-----------------------------|------------------------------------|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 229 | 231 ^[2] | | |
| Units: Percentage | | | | |
| number (not applicable) | | | | |
| 1-year survival | 93.4 | 98.3 | | |
| 2-year survival | 82.6 | 96.1 | | |

| | | | | |
|---------------------|------|------|--|--|
| 3-year survival | 75.9 | 91.3 | | |
| 4-year survival | 60.8 | 85.9 | | |
| 5-year survival | 50.7 | 81.3 | | |
| Median PFS (months) | 61.2 | 0 | | |

Notes:

[2] - Median PFS was not reached in this subgroup

Statistical analyses

| | |
|-----------------------------------|---|
| Statistical analysis title | Two-sided stratified log-rank test (GIVe vs SCIT) |
|-----------------------------------|---|

Statistical analysis description:

PFS treatment comparison of GIVe and SCIT will be performed using a two-sided stratified log-rank test (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). The co-primary endpoint PFS [GIVe vs. SCIT] has been formally tested during the "interim analysis of the co-primary endpoint PFS" with the data cut-off 2022.01.20. There is no alpha spend in the current analysis of the co-primary endpoint [PFS: GIVe vs. SCIT].

| | |
|---|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Logrank |

| | |
|-----------------------------------|-------------------------------|
| Statistical analysis title | Cox regression (GIVe vs SCIT) |
|-----------------------------------|-------------------------------|

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

| | |
|---|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzmab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.344 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.235 |
| upper limit | 0.503 |

Primary: MRD negativity in peripheral blood at month 15 [GIVe versus SCIT]

| | |
|-----------------|--|
| End point title | MRD negativity in peripheral blood at month 15 [GIVe versus SCIT] ^[3] |
|-----------------|--|

End point description:

One co-primary objective of the study is to assess the MRD negativity rate. MRD negativity is defined as <1 CLL-cell among 10,000 leukocytes analyzed [0.01%], i.e. < 10⁻⁴. Values above [≥10⁻⁴] will be considered as MRD positive.

The MRD negativity rate in PB at MO 15 is defined as the proportion of MRD negative patients at MO 15 based on the ITT population (= number of MRD negative patients divided by the number of the ITT population). Patients without an MRD sample in peripheral blood at MO 15 will be counted as MRD positive patients.

| | |
|-------------------------------------|---------|
| End point type | Primary |
| End point timeframe: | |
| 15 months after start of treatment. | |

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The statistics for the comparisons of the other arms are reported in a separate endpoint as only the comparison between GVE versus SCIT was considered as primary endpoint in this analysis. The other comparisons are considered as secondary endpoint and are reported as secondary endpoint accordingly.

| End point values | Standard chemoimmunotherapy (SCIT) | Venetoclax, rituximab (RVe) | | |
|------------------------------------|------------------------------------|-----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 229 | 229 | | |
| Units: percentage | | | | |
| number (confidence interval 97.5%) | | | | |
| MRD negativity rate | 52 (44.4 to 59.5) | 86.5 (80.6 to 91.1) | | |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Cochran-Mantel-Haenszel test (GVe vs SCIT) |
|----------------------------|--|

Statistical analysis description:

MRD negativity rate of GVe and SCIT will be compared using Cochran-Mantel-Haenszel test stratified by age (with a cut-off of 65 years) and Binet stage. The co-primary endpoint MRD in PB at MO15 [GVe vs. SCIT] has been formally tested during the "co-primary endpoint analysis of MRD negativity rate at month 15" with the data cut-off 2021.02.28. There is no alpha spend in the current analysis of the co-primary endpoint [MRD in PB at MO15: GVe vs. SCIT].

| | |
|---|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 458 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Cochran-Mantel-Haenszel |

Secondary: Overall survival (OS)

| | |
|-----------------|-----------------------|
| End point title | Overall survival (OS) |
|-----------------|-----------------------|

End point description:

Overall survival will be measured from the date of randomization to the date of death due to any cause. Patients who have not yet died at the time of analysis will be censored at the time of last observation they were assessed to be alive.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Data for this endpoint will be collected from the date of randomization until last visit of each study

| End point values | Standard chemoimmunotherapy (SCIT) | Venetoclax, rituximab (RVe) | Venetoclax, obinutuzumab (GVe) | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
|-----------------------------|------------------------------------|-----------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 229 ^[4] | 237 ^[5] | 229 ^[6] | 231 ^[7] |
| Units: percent | | | | |
| number (not applicable) | | | | |
| 1-year survival | 99.1 | 97.9 | 99.1 | 98.7 |
| 2-year survival | 98.6 | 97.9 | 98.2 | 97 |
| 3-year survival | 95.7 | 96.6 | 96.5 | 95.6 |
| 4-year survival | 93.8 | 96.2 | 95.2 | 94.7 |
| 5-year survival | 90.7 | 94.7 | 93.6 | 94.3 |
| Median OS (months) | 0 | 0 | 0 | 0 |

Notes:

[4] - Median OS was not reached in this subgroup

[5] - Median OS was not reached in this subgroup

[6] - Median OS was not reached in this subgroup

[7] - Median OS was not reached in this subgroup

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Two-sided log-rank test (GIVe vs SCIT) |
| Statistical analysis description: | |
| Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints. | |
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.175 |
| Method | Logrank |

| | |
|---|---|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs SCIT) |
| Statistical analysis description: | |
| Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model. | |
| Comparison groups | Venetoclax, obinutuzumab, ibrutinib (GIVe) v Standard chemoimmunotherapy (SCIT) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.617 |

| | |
|---------------------|---------------|
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.275 |
| upper limit | 1.382 |

| | |
|-----------------------------------|---------------------------------------|
| Statistical analysis title | Two-sided log-rank test (GVe vs SCIT) |
|-----------------------------------|---------------------------------------|

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

| | |
|---|---|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab (GVe) |
| Number of subjects included in analysis | 458 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.423 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (GVe vs SCIT) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|---|---|
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Standard chemoimmunotherapy (SCIT) |
| Number of subjects included in analysis | 458 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.762 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.356 |
| upper limit | 1.631 |

| | |
|-----------------------------------|---------------------------------------|
| Statistical analysis title | Two-sided log-rank test (RVe vs SCIT) |
|-----------------------------------|---------------------------------------|

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

| | |
|-------------------|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe) |
|-------------------|--|

| | |
|---|---------------|
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.255 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (RVe vs SCIT) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|---|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.676 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.312 |
| upper limit | 1.468 |

| | |
|-----------------------------------|---------------------------------------|
| Statistical analysis title | Two-sided log-rank test (GIVe vs GVe) |
|-----------------------------------|---------------------------------------|

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

| | |
|---|--|
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.564 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs GVe) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|-------------------|--|
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzmab, ibrutinib (GIVe) |
|-------------------|--|

| | |
|---|-------------------------|
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.806 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.349 |
| upper limit | 1.862 |

| | |
|--|--|
| Statistical analysis title | Two-sided log-rank test (GVe vs RVe) |
| Statistical analysis description: | |
| Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints. | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.678 |
| Method | Logrank |

| | |
|---|--|
| Statistical analysis title | Cox proportional hazards analysis (GVe vs RVe) |
| Statistical analysis description: | |
| Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model. | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 1.162 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.517 |
| upper limit | 2.613 |

| | |
|--|--|
| Statistical analysis title | Two-sided log-rank test (GIVe vs RVe) |
| Statistical analysis description: | |
| Treatment comparison for the secondary efficacy parameter OS will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints. | |
| Comparison groups | Venetoclax, obinutuzumab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe) |

| | |
|---|---------------|
| Number of subjects included in analysis | 468 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.784 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs RVe) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|---|---|
| Comparison groups | Venetoclax, obinutuzmab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 468 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.901 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.385 |
| upper limit | 2.108 |

Secondary: Time to next treatment (TTNT)

| | |
|-----------------|-------------------------------|
| End point title | Time to next treatment (TTNT) |
|-----------------|-------------------------------|

End point description:

TTNT will be measured from the date of randomization until the date of first anti-leukemic treatment. Patients for whom no subsequent anti-leukemic treatment is documented will be censored at the time of last observation they were assessed to be free from subsequent treatment.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Data for this endpoint will be collected from the date of randomization until last visit of each study subject.

| End point values | Standard chemoimmunotherapy (SCIT) | Venetoclax, rituximab (RVe) | Venetoclax, obinutuzumab (GVe) | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
|-----------------------------|------------------------------------|-----------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 229 ^[8] | 237 ^[9] | 229 ^[10] | 231 ^[11] |
| Units: percent | | | | |
| number (not applicable) | | | | |
| 1-year survival | 97.7 | 97.9 | 98.7 | 100 |
| 2-year survival | 93.4 | 95.3 | 97.8 | 100 |
| 3-year survival | 87.1 | 91.8 | 94.6 | 98.6 |
| 4-year survival | 77.5 | 83.9 | 90 | 95.4 |

| | | | | |
|-----------------|------|------|------|------|
| 5-year survival | 67.1 | 77.1 | 87.5 | 92.6 |
| Median months | 0 | 0 | 0 | 0 |

Notes:

[8] - Median TTNT was not reached in this subgroup

[9] - Median TTNT was not reached in this subgroup

[10] - Median TTNT was not reached in this subgroup

[11] - Median TTNT was not reached in this subgroup

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Two-sided log-rank test (GIVe vs SCIT) |
| Statistical analysis description: | |
| Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints. | |
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.0001 |
| Method | Logrank |

| | |
|---|---|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs SCIT) |
| Statistical analysis description: | |
| Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model. | |
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.218 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.123 |
| upper limit | 0.386 |

| | |
|--|---|
| Statistical analysis title | Two-sided log-rank test (GVe vs SCIT) |
| Statistical analysis description: | |
| Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints. | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Standard chemoimmunotherapy (SCIT) |

| | |
|---|---------------|
| Number of subjects included in analysis | 458 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.0001 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (GVe vs SCIT) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|---|---|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab (GVe) |
| Number of subjects included in analysis | 458 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.429 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.273 |
| upper limit | 0.676 |

| | |
|-----------------------------------|---------------------------------------|
| Statistical analysis title | Two-sided log-rank test (RVe vs SCIT) |
|-----------------------------------|---------------------------------------|

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

| | |
|---|--|
| Comparison groups | Venetoclax, rituximab (RVe) v Standard chemoimmunotherapy (SCIT) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.204 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (RVe vs SCIT) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|-------------------|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe) |
|-------------------|--|

| | |
|---|-------------------------|
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.806 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.55 |
| upper limit | 1.181 |

| | |
|-----------------------------------|---------------------------------------|
| Statistical analysis title | Two-sided log-rank test (GIVe vs GVe) |
|-----------------------------------|---------------------------------------|

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

| | |
|---|---|
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.01 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs GVe) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|---|---|
| Comparison groups | Venetoclax, obinutuzumab, ibrutinib (GIVe) v Venetoclax, obinutuzumab (GVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.498 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.268 |
| upper limit | 0.925 |

| | |
|-----------------------------------|--------------------------------------|
| Statistical analysis title | Two-sided log-rank test (GVe vs RVe) |
|-----------------------------------|--------------------------------------|

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

| | |
|-------------------|--|
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe) |
|-------------------|--|

| | |
|---|---------------|
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.0014 |
| Method | Logrank |

| | |
|-----------------------------------|--|
| Statistical analysis title | Cox proportional hazards analysis (GVe vs RVe) |
|-----------------------------------|--|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|---|--|
| Comparison groups | Venetoclax, rituximab (Rve) v Venetoclax, obinutuzumab (Gve) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.529 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.337 |
| upper limit | 0.833 |

| | |
|-----------------------------------|---------------------------------------|
| Statistical analysis title | Two-sided log-rank test (GIVe vs RVe) |
|-----------------------------------|---------------------------------------|

Statistical analysis description:

Treatment comparison for the secondary efficacy parameter TTNT will be performed using a two-sided non-stratified log-rank test. There is no alpha spend in the analysis of secondary endpoints.

| | |
|---|--|
| Comparison groups | Venetoclax, rituximab (Rve) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 468 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.0001 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs RVe) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed by the hazard ratio (HR) including the 97.5% confidence interval estimated through a non-stratified Cox proportional hazard regression model.

| | |
|-------------------|--|
| Comparison groups | Venetoclax, rituximab (Rve) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
|-------------------|--|

| | |
|---|-------------------------|
| Number of subjects included in analysis | 468 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.266 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.151 |
| upper limit | 0.471 |

Secondary: Response rate at month 15

| | |
|---|---------------------------|
| End point title | Response rate at month 15 |
| End point description: The overall response rate (ORR) will be defined as the proportion of patients having achieved a CR/CRi, clinical CR/CRi or PR (including PR with lymphocytosis) (according to the iwCLL guidelines (2008)) at MO 15 (= number of patients with response CR/CRi, clinical CR/CRi or PR (with or without lymphocytosis) divided by the ITT population). | |
| End point type | Secondary |
| End point timeframe: 15 months after start of treatment. | |

| End point values | Standard chemoimmunotherapy (SCIT) | Venetoclax, rituximab (RVe) | Venetoclax, obinutuzumab (GVe) | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
|-----------------------------|------------------------------------|-----------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 229 | 237 | 229 | 231 |
| Units: Patients | | | | |
| CR | 73 | 112 | 124 | 128 |
| CRi | 9 | 2 | 4 | 9 |
| Clinical CR | 51 | 29 | 21 | 24 |
| Clinical CRi | 5 | 0 | 3 | 4 |
| PR | 47 | 78 | 68 | 53 |
| SD | 3 | 0 | 0 | 0 |
| PD | 7 | 1 | 2 | 1 |
| Missing | 34 | 15 | 7 | 12 |

Statistical analyses

No statistical analyses for this end point

Secondary: PFS (all other comparisons except for [GIVe versus SCIT])

| | |
|-----------------|---|
| End point title | PFS (all other comparisons except for [GIVe versus SCIT]) |
|-----------------|---|

End point description:

Progression-free survival is defined as the time from randomization to the first occurrence of progression or relapse (determined using standard IWCLL guidelines [2008]), or death from any cause, whichever occurs first. For patients who have not progressed, relapsed, or died at the time of analysis, PFS will be censored on the date of the last tumor assessment. In case of initiation of subsequent anti-leukemic treatment without documented disease progression patient will be censored at last tumor assessment prior to start of subsequent therapy. If no tumor assessments were performed after the screening visit, PFS will be censored at the time of randomization + 1 day.

Median PFS and the 97.5% CI will be estimated using Kaplan-Meier survival methodology, with the Kaplan-Meier survival curve presented to provide a visual description. PFS rates for 1, 2 and 3 years etc. after randomization will be reported.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Data will be collected from randomization until last visit of each study subject | |

| End point values | Standard chemoimmunotherapy (SCIT) | Venetoclax, rituximab (RVe) | Venetoclax, obinutuzumab (GVe) | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
|-----------------------------|------------------------------------|-----------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 229 | 237 | 229 ^[12] | 231 ^[13] |
| Units: percent | | | | |
| number (not applicable) | | | | |
| 1-year survival | 93.4 | 96.6 | 97.4 | 98.3 |
| 2-year survival | 82.6 | 91.9 | 92.5 | 96.1 |
| 3-year survival | 75.9 | 80.7 | 88.6 | 91.3 |
| 4-year survival | 60.8 | 71.1 | 81.9 | 85.9 |
| 5-year survival | 50.7 | 57.4 | 69.8 | 81.3 |
| Median PFS (months) | 61.2 | 64.5 | 0 | 0 |

Notes:

[12] - Median PFS was not reached in this subgroup

[13] - Median PFS was not reached in this subgroup

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Two-sided log-rank test (GVe vs SCIT) |
| Statistical analysis description: | |
| PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS. | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Standard chemoimmunotherapy (SCIT) |
| Number of subjects included in analysis | 458 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.0001 |
| Method | Logrank |

| | |
|-----------------------------------|---|
| Statistical analysis title | Cox proportional hazards analysis (GVe vs SCIT) |
|-----------------------------------|---|

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

| | |
|---|---|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab (GVe) |
| Number of subjects included in analysis | 458 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.544 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.389 |
| upper limit | 0.761 |

Statistical analysis title

Two-sided log-rank test (RVe vs SCIT)

Statistical analysis description:

PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS.

| | |
|---|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.53 |
| Method | Logrank |

Statistical analysis title

Cox proportional hazards analysis (RVe vs SCIT)

Statistical analysis description:

Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage).

| | |
|---|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.919 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.681 |
| upper limit | 1.241 |

| | |
|--|---|
| Statistical analysis title | Two-sided log-rank test (GIVe vs GVe) |
| Statistical analysis description: PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS. | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.0046 |
| Method | Logrank |

| | |
|---|---|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs GVe) |
| Statistical analysis description: Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.607 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.407 |
| upper limit | 0.905 |

| | |
|--|--|
| Statistical analysis title | Two-sided log-rank test (GVe vs RVe) |
| Statistical analysis description: PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS. | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.00019 |
| Method | Logrank |

| | |
|--|--|
| Statistical analysis title | Cox proportional hazards analysis (GVe vs RVe) |
| Statistical analysis description: | |
| Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). | |
| Comparison groups | Venetoclax, obinutuzumab (GVe) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.586 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.424 |
| upper limit | 0.811 |

| | |
|---|--|
| Statistical analysis title | Two-sided log-rank test (GIVe vs RVe) |
| Statistical analysis description: | |
| PFS treatment comparisons will be performed using two-sided stratified log-rank tests (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). There is no alpha spend in the current analysis of the co-primary endpoint of PFS. | |
| Comparison groups | Venetoclax, obinutuzumab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 468 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.0001 |
| Method | Logrank |

| | |
|--|--|
| Statistical analysis title | Cox proportional hazards analysis (GIVe vs RVe) |
| Statistical analysis description: | |
| Estimates of the treatment effect will be expressed as HR including 97.5% CI estimated through a stratified Cox proportional hazards analysis (considering the stratification factors age (with a cut-off of 65 years) and Binet stage). | |
| Comparison groups | Venetoclax, obinutuzumab, ibrutinib (GIVe) v Venetoclax, rituximab (RVe) |
| Number of subjects included in analysis | 468 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Cox proportional hazard |
| Point estimate | 0.347 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.238 |
| upper limit | 0.506 |

Secondary: MRD negativity in peripheral blood at month 15 (except for [GVe versus SCIT])

| | |
|--|---|
| End point title | MRD negativity in peripheral blood at month 15 (except for [GVe versus SCIT]) |
| End point description: MRD negativity is defined as <1 CLL-cell among 10,000 leukocytes analyzed [0.01%], i.e. < 10 ⁻⁴ . Values above [≥10 ⁻⁴] will be considered as MRD positive. The MRD negativity rate in PB at MO 15 is defined as the proportion of MRD negative patients at MO 15 based on the ITT population (= number of MRD negative patients divided by the number of the ITT population). Patients without an MRD sample in peripheral blood at MO 15 will be counted as MRD positive patients. | |
| End point type | Secondary |
| End point timeframe: 15 months after start of treatment. | |

| End point values | Standard chemoimmunotherapy (SCIT) | Venetoclax, rituximab (RVe) | Venetoclax, obinutuzumab (GVe) | Venetoclax, obinutuzumab, ibrutinib (GIVe) |
|------------------------------------|------------------------------------|-----------------------------|--------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 229 | 237 | 229 | 231 |
| Units: percent | | | | |
| number (confidence interval 97.5%) | | | | |
| MRD negativity rate | 52 (44.4 to 59.5) | 57 (49.5 to 64.2) | 86.5 (80.6 to 91.1) | 92.2 (87.3 to 95.7) |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Cochran-Mantel-Haenszel test (GIVe vs SCIT) |
| Statistical analysis description: MRD negativity rates of treatment groups will be compared using Cochran-Mantel-Haenszel test stratified by age (with a cut-off of 65 years) and Binet stage. There is no alpha spend in the current analysis of the co-primary endpoint of MRD negativity rate at month 15. | |
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, obinutuzumab, ibrutinib (GIVe) |
| Number of subjects included in analysis | 460 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | < 0.0001 |
| Method | Cochran-Mantel-Haenszel |

| | |
|---|--|
| Statistical analysis title | Cochran-Mantel-Haenszel test (RVe vs SCIT) |
| Statistical analysis description: MRD negativity rates of treatment groups will be compared using Cochran-Mantel-Haenszel test | |

stratified by age (with a cut-off of 65 years) and Binet stage. There is no alpha spend in the current analysis of the co-primary endpoint of MRD negativity rate at month 15.

| | |
|---|--|
| Comparison groups | Standard chemoimmunotherapy (SCIT) v Venetoclax, rituximab (RvE) |
| Number of subjects included in analysis | 466 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.317 |
| Method | Cochran-Mantel-Haenszel |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Timeframe for AE

Adverse event reporting additional description:

AE additional description

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 19.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | GVe arm |
|-----------------------|---------|

Reporting group description: -

| | |
|-----------------------|----------|
| Reporting group title | SCIT arm |
|-----------------------|----------|

Reporting group description: -

| | |
|-----------------------|---------|
| Reporting group title | RVe arm |
|-----------------------|---------|

Reporting group description: -

| | |
|-----------------------|----------|
| Reporting group title | GIVe arm |
|-----------------------|----------|

Reporting group description: -

| Serious adverse events | GVe arm | SCIT arm | RVe arm |
|---|---|--------------------|--------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 136 / 228 (59.65%) | 145 / 216 (67.13%) | 131 / 237 (55.27%) |
| number of deaths (all causes) | 15 | 19 | 15 |
| number of deaths resulting from adverse events | 14 | 18 | 14 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute myeloid leukaemia | Additional description: Acute myeloid leukaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Adenocarcinoma pancreas | Additional description: Adenocarcinoma pancreas | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Basal cell carcinoma | Additional description: Basal cell carcinoma | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 4 / 216 (1.85%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 1 / 3 | 3 / 5 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|--|-----------------|-----------------|
| Bladder cancer | Additional description: Bladder cancer | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Bowen's disease | Additional description: Bowen's disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Breast cancer | Additional description: Breast cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chondrosarcoma | Additional description: Chondrosarcoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Central nervous system leukaemia | Additional description: Central nervous system leukaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon cancer | Additional description: Colon cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Dedifferentiated liposarcoma | Additional description: Dedifferentiated liposarcoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Follicular lymphoma | Additional description: Follicular lymphoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Glioblastoma | Additional description: Glioblastoma | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Hepatocellular carcinoma | Additional description: Hepatocellular carcinoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Hypopharyngeal cancer | Additional description: Hypopharyngeal cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Lipoma | Additional description: Lipoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm of unknown primary site | Additional description: Malignant neoplasm of unknown primary site | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Lung adenocarcinoma | Additional description: Lung adenocarcinoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung neoplasm malignant | Additional description: Lung neoplasm malignant | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Malignant melanoma | Additional description: Malignant melanoma | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Mantle cell lymphoma | Additional description: Mantle cell lymphoma | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningioma | Additional description: Meningioma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningioma benign | Additional description: Meningioma benign | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastatic gastric cancer | Additional description: Metastatic gastric cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Myelodysplastic syndrome | Additional description: Myelodysplastic syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Myxoid liposarcoma | Additional description: Myxoid liposarcoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-small cell lung cancer | Additional description: Non-small cell lung cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oesophageal adenocarcinoma | Additional description: Oesophageal adenocarcinoma | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Oesophageal carcinoma | Additional description: Oesophageal carcinoma | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ovarian adenoma | Additional description: Ovarian adenoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Phaeochromocytoma | Additional description: Phaeochromocytoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Plasma cell myeloma | Additional description: Plasma cell myeloma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Papillary thyroid cancer | Additional description: Papillary thyroid cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polycythaemia vera | Additional description: Polycythaemia vera | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate cancer | Additional description: Prostate cancer | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 3 / 216 (1.39%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Prostate cancer metastatic | Additional description: Prostate cancer metastatic | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Rectal adenocarcinoma | Additional description: Rectal adenocarcinoma | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal cancer | Additional description: Rectal cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal Cell Carcinoma | Additional description: Renal Cell Carcinoma | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Richter's syndrome | Additional description: Richter's syndrome | | |
| subjects affected / exposed | 7 / 228 (3.07%) | 5 / 216 (2.31%) | 6 / 237 (2.53%) |
| occurrences causally related to treatment / all | 0 / 7 | 1 / 5 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 2 | 1 / 3 | 0 / 4 |
| Salivary gland adenoma | Additional description: Salivary gland adenoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| 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 | Additional description: Salivary gland cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seborrhoeic keratosis | Additional description: Seborrhoeic keratosis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | Additional description: Squamous cell carcinoma of skin | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin squamous cell carcinoma metastatic | Additional description: Skin squamous cell carcinoma metastatic | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| Small cell lung cancer | Additional description: Small cell lung cancer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Soft tissue sarcoma | Additional description: Soft tissue sarcoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal cord neoplasm | Additional description: Spinal cord neoplasm | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma | Additional description: Squamous cell carcinoma | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 6 / 216 (2.78%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 2 / 6 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Uterine leiomyoma | Additional description: Uterine leiomyoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Aortic aneurysm | Additional description: Aortic aneurysm | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aortic stenosis | Additional description: Aortic stenosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blue toe syndrome | Additional description: Blue toe syndrome | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Deep vein thrombosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Hypertension | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypertensive crisis | Additional description: Hypertensive crisis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | Additional description: Hypotension | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Orthostatic hypotension | Additional description: Orthostatic hypotension | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral arterial occlusive disease | Additional description: Peripheral arterial occlusive disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral ischaemia | Additional description: Peripheral ischaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyarteritis nodosa | Additional description: Polyarteritis nodosa | | |

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|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombophlebitis | Additional description: Thrombophlebitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Surgical and medical procedures | | | |
| Chest tube removal | Additional description: Chest tube removal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystectomy | Additional description: Cholecystectomy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coronary arterial stent insertion | Additional description: Coronary arterial stent insertion | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coronary artery bypass | Additional description: Coronary artery bypass | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epidermoid cyst excision | Additional description: Epidermoid cyst excision | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ethmoid sinus surgery | Additional description: Ethmoid sinus surgery | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrectomy | Additional description: Gastrectomy | | |

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|--|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hip arthroplasty | Additional description: Hip arthroplasty | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hip surgery | Additional description: Hip surgery | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Adverse drug reaction | Additional description: Adverse drug reaction | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Asthenia | Additional description: Asthenia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest pain | Additional description: Chest pain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Death | Additional description: Death | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Fatigue | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| General physical health deterioration | Additional description: General physical health deterioration | | |

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|---|---|------------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza like illness | Additional description: Influenza like illness | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | Additional description: Malaise | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Oedema peripheral | Additional description: Oedema peripheral | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Puncture site haematoma | Additional description: Puncture site haematoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Pyrexia | | |
| subjects affected / exposed | 8 / 228 (3.51%) | 10 / 216 (4.63%) | 8 / 237 (3.38%) |
| occurrences causally related to treatment / all | 7 / 8 | 11 / 12 | 5 / 8 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | Additional description: Anaphylactic reaction | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytokine release syndrome | Additional description: Cytokine release syndrome | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Drug hypersensitivity | Additional description: Drug hypersensitivity | | |

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|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersensitivity | Additional description: Hypersensitivity | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Sarcoidosis | Additional description: Sarcoidosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | Additional description: Benign prostatic hyperplasia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Genital prolapse | Additional description: Genital prolapse | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Menorrhagia | Additional description: Menorrhagia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectocele | Additional description: Rectocele | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | | | |
| Bronchial obstruction | Additional description: Bronchial obstruction | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |

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| Bronchitis chronic | Additional description: Bronchitis chronic | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | Additional description: Dyspnoea | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nasal septum disorder | Additional description: Nasal septum disorder | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Obliterative bronchiolitis | Additional description: Obliterative bronchiolitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | Additional description: Pleural effusion | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Pleuritic pain | Additional description: Pleuritic pain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | Additional description: Pneumonitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Pneumothorax | Additional description: Pneumothorax | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | Additional description: Pulmonary embolism | | |

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|---|---|-----------------|-----------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 2 / 216 (0.93%) | 3 / 237 (1.27%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary fibrosis | Additional description: Pulmonary fibrosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary mass | Additional description: Pulmonary mass | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | Additional description: Respiratory failure | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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-airway cough syndrome | Additional description: Upper-airway cough syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| 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 | | | |
| Completed suicide | Additional description: Completed suicide | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Delirium | Additional description: Delirium | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Depression | Additional description: Depression | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Insomnia | Additional description: Insomnia | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicide attempt | Additional description: Suicide attempt | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Blood lactate dehydrogenase increased | Additional description: Blood lactate dehydrogenase increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 3 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood creatine increased | Additional description: Blood creatine increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood creatine phosphokinase increased | Additional description: Blood creatine phosphokinase increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Blood creatinine increased | Additional description: Blood creatinine increased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood phosphorus increased | Additional description: Blood phosphorus increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Blood potassium increased | Additional description: Blood potassium increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic enzyme increased | Additional description: Hepatic enzyme increased | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Medical observation | Additional description: Medical observation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 necrosis marker increased | Additional description: Myocardial necrosis marker increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| N-terminal prohormone brain natriuretic peptide increased | Additional description: N-terminal prohormone brain natriuretic peptide increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Prostatic specific antigen increased | Additional description: Prostatic specific antigen increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SARS-CoV-2 test positive | Additional description: SARS-CoV-2 test positive | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transaminases increased | Additional description: Transaminases increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Alcohol poisoning | Additional description: Alcohol poisoning | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
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| Ankle fracture | Additional description: Ankle fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Forearm fracture | Additional description: Forearm fracture | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Facial bones fracture | Additional description: Facial bones fracture | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | Additional description: Fall | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femoral neck fracture | Additional description: Femoral neck fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | Additional description: Femur fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fibula fracture | Additional description: Fibula fracture | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foot fracture | Additional description: Foot fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Hand fracture | Additional description: Hand fracture | | |

| | | | |
|---|---|-----------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hip fracture | Additional description: Hip fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Humerus fracture | Additional description: Humerus fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infusion related reaction | Additional description: Infusion related reaction | | |
| subjects affected / exposed | 20 / 228 (8.77%) | 9 / 216 (4.17%) | 20 / 237 (8.44%) |
| occurrences causally related to treatment / all | 22 / 22 | 10 / 12 | 22 / 22 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Kidney rupture | Additional description: Kidney rupture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lumbar vertebral fracture | Additional description: Lumbar vertebral fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Multiple fractures | Additional description: Multiple fractures | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| 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 | Additional description: Multiple injuries | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meniscus injury | Additional description: Meniscus injury | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural haematoma | Additional description: Post procedural haematoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Procedural intestinal perforation | Additional description: Procedural intestinal perforation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reactive gastropathy | Additional description: Reactive gastropathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Silicosis | Additional description: Silicosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Road traffic accident | Additional description: Road traffic accident | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 fracture | Additional description: Skull fracture | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | Additional description: Spinal compression fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Spinal fracture | Additional description: Spinal fracture | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | Additional description: Thermal burn | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Subdural haematoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thoracic vertebral fracture | Additional description: Thoracic vertebral fracture | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Tibia fracture | Additional description: Tibia fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ulna fracture | Additional description: Ulna fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrist fracture | Additional description: Wrist fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | | | |
| Adenomatous polyposis coli | Additional description: Adenomatous polyposis coli | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |

| | | | |
|--|--|-----------------|-----------------|
| Acute coronary syndrome subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Acute coronary syndrome | | |
| | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| | 0 / 0 | 1 / 1 | 0 / 0 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute myocardial infarction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Acute myocardial infarction | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial tachycardia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Atrial tachycardia | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Aortic valve disease subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Aortic valve disease | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 / 0 | 0 / 0 | 0 / 1 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Arteriosclerosis coronary artery subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Arteriosclerosis coronary artery | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 / 0 | 0 / 0 | 0 / 1 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Atrial fibrillation | | |
| | 3 / 228 (1.32%) | 7 / 216 (3.24%) | 3 / 237 (1.27%) |
| | 2 / 4 | 2 / 7 | 0 / 3 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial flutter subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Atrial flutter | | |
| | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| | 0 / 0 | 0 / 1 | 0 / 1 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Angina pectoris subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Angina pectoris | | |
| | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| | 0 / 2 | 2 / 4 | 0 / 0 |
| | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrioventricular block | Additional description: Atrioventricular block | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac arrest | Additional description: Cardiac arrest | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| Cardiac failure | Additional description: Cardiac failure | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Cardiac failure congestive | Additional description: Cardiac failure congestive | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Cardiomyopathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coronary artery disease | Additional description: Coronary artery disease | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intracardiac thrombus | Additional description: Intracardiac thrombus | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | Additional description: Myocardial infarction | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocarditis | Additional description: Myocarditis | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericarditis | Additional description: Pericarditis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Palpitations | Additional description: Palpitations | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | Additional description: Pericardial effusion | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinus node dysfunction | Additional description: Sinus node dysfunction | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stress cardiomyopathy | Additional description: Stress cardiomyopathy | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Supraventricular tachycardia | Additional description: Supraventricular tachycardia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ventricular fibrillation | Additional description: Ventricular fibrillation | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Carotid artery stenosis | Additional description: Carotid artery stenosis | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Carotid artery occlusion | Additional description: Carotid artery occlusion | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebellar stroke | Additional description: Cerebellar stroke | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Cerebral haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral ischaemia | Additional description: Cerebral ischaemia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | Additional description: Cerebrovascular accident | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysaesthesia | Additional description: Dysaesthesia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dizziness | Additional description: Dizziness | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolic cerebral infarction | Additional description: Embolic cerebral infarction | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Encephalitis autoimmune | Additional description: Encephalitis autoimmune | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epilepsy | Additional description: Epilepsy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemorrhagic stroke | Additional description: Haemorrhagic stroke | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Headache | Additional description: Headache | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Ischaemic stroke | Additional description: Ischaemic stroke | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Myasthenia gravis | Additional description: Myasthenia gravis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polyneuropathy | Additional description: Polyneuropathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | Additional description: Seizure | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | Additional description: Syncope | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombotic stroke | Additional description: Thrombotic stroke | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Toxic leukoencephalopathy | Additional description: Toxic leukoencephalopathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient global amnesia | Additional description: Transient global amnesia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | Additional description: Transient ischaemic attack | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vocal cord paresis | Additional description: Vocal cord paresis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | Additional description: Anaemia | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 4 / 216 (1.85%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 1 / 2 | 2 / 4 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aplasia pure red cell | Additional description: Aplasia pure red cell | | |

| | | | |
|---|---|------------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Autoimmune haemolytic anaemia | Additional description: Autoimmune haemolytic anaemia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Autoimmune neutropenia | Additional description: Autoimmune neutropenia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | Additional description: Febrile neutropenia | | |
| subjects affected / exposed | 8 / 228 (3.51%) | 21 / 216 (9.72%) | 7 / 237 (2.95%) |
| occurrences causally related to treatment / all | 6 / 8 | 23 / 26 | 7 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemolytic anaemia | Additional description: Haemolytic anaemia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune thrombocytopenia | Additional description: Immune thrombocytopenia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Leukostasis syndrome | Additional description: Leukostasis syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Lymphadenitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphocytosis | Additional description: Lymphocytosis | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Neutropenia | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 2 / 216 (0.93%) | 3 / 237 (1.27%) |
| occurrences causally related to treatment / all | 4 / 4 | 2 / 2 | 4 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancytopenia | Additional description: Pancytopenia | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 2 / 2 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Splenomegaly | Additional description: Splenomegaly | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | Additional description: Thrombocytopenia | | |
| subjects affected / exposed | 8 / 228 (3.51%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 7 / 8 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| Vertigo | Additional description: Vertigo | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vertigo positional | Additional description: Vertigo positional | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 disorders | | | |
| Acute macular outer retinopathy | Additional description: Acute macular outer retinopathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cataract | Additional description: Cataract | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dacryostenosis acquired | Additional description: Dacryostenosis acquired | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid cyst | Additional description: Eyelid cyst | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Macular hole | Additional description: Macular hole | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Optic ischaemic neuropathy | Additional description: Optic ischaemic neuropathy | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Retinal detachment | Additional description: Retinal detachment | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Venous stasis retinopathy | Additional description: Venous stasis retinopathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| 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 disorders | | | |
| Abdominal pain | Additional description: Abdominal pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal hernia | Additional description: Abdominal hernia | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | Additional description: Abdominal pain upper | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Diarrhoea | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diverticulum intestinal | Additional description: Diverticulum intestinal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Duodenal perforation | Additional description: Duodenal perforation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 haemorrhage | Additional description: Duodenal ulcer haemorrhage | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enlarged uvula | Additional description: Enlarged uvula | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Epiploic appendagitis | Additional description: Epiploic appendagitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erosive oesophagitis | Additional description: Erosive oesophagitis | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Gastritis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis erosive | Additional description: Gastritis erosive | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | Additional description: Gastrointestinal haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrooesophageal reflux disease | Additional description: Gastrooesophageal reflux disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 erosive gastritis | Additional description: Haemorrhagic erosive gastritis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | Additional description: Ileus | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Impaired gastric emptying | Additional description: Impaired gastric emptying | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Inguinal hernia | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 3 / 216 (1.39%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Irritable bowel syndrome | Additional description: Irritable bowel syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| 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 | Additional description: Nausea | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 2 | 2 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oesophageal rupture | Additional description: Oesophageal rupture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Pancreatitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatolithiasis | Additional description: Pancreatolithiasis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Stomatitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper gastrointestinal haemorrhage | Additional description: Upper gastrointestinal haemorrhage | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Bile duct stenosis | Additional description: Bile duct stenosis | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary colic | Additional description: Biliary colic | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Cholecystitis | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 4 / 216 (1.85%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholecystitis acute | Additional description: Cholecystitis acute | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholelithiasis | Additional description: Cholelithiasis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gallbladder polyp | Additional description: Gallbladder polyp | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatotoxicity | Additional description: Hepatotoxicity | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Liver disorder | Additional description: Liver disorder | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Subcapsular hepatic haematoma | Additional description: Subcapsular hepatic haematoma | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| 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 and subcutaneous tissue disorders | | | |
| Actinic keratosis | Additional description: Actinic keratosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dermatitis | Additional description: Dermatitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Dermatitis allergic | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erythema multiforme | Additional description: Erythema multiforme | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | Additional description: Rash | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Rash maculo-papular | Additional description: Rash maculo-papular | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Renal and urinary disorders | | | |
| Acute kidney injury | Additional description: Acute kidney injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Nephrolithiasis | Additional description: Nephrolithiasis | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal colic | Additional description: Renal colic | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Ureterolithiasis | Additional description: Ureterolithiasis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urethral caruncle | Additional description: Urethral caruncle | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urethral stenosis | Additional description: Urethral stenosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary retention | Additional description: Urinary retention | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Goitre | Additional description: Goitre | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperthyroidism | Additional description: Hyperthyroidism | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|--|-----------------|-----------------|
| Arthralgia | Additional description: Arthralgia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Back pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bursitis | Additional description: Bursitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dupuytren's contracture | Additional description: Dupuytren's contracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gouty arthritis | Additional description: Gouty arthritis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haemarthrosis | Additional description: Haemarthrosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematoma muscle | Additional description: Haematoma muscle | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Hypercreatinaemia | Additional description: Hypercreatinaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Intervertebral disc protrusion | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| 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 pain | Additional description: Musculoskeletal pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Pain in extremity | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Osteochondrosis | Additional description: Osteochondrosis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteonecrosis | Additional description: Osteonecrosis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteoporotic fracture | Additional description: Osteoporotic fracture | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteoarthritis | Additional description: Osteoarthritis | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Periarthritis | Additional description: Periarthritis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Polymyalgia rheumatica | Additional description: Polymyalgia rheumatica | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Rotator cuff syndrome | Additional description: Rotator cuff syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scleroderma | Additional description: Scleroderma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 column stenosis | Additional description: Spinal column stenosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 pain | Additional description: Spinal pain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tenosynovitis | Additional description: Tenosynovitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Anal abscess | Additional description: Anal abscess | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abscess limb | Additional description: Abscess limb | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abscess | Additional description: Abscess | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Appendicitis | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis perforated | Additional description: Appendicitis perforated | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asymptomatic COVID-19 | Additional description: Asymptomatic COVID-19 | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | Additional description: Bacteraemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Bacterial infection | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Atypical pneumonia | Additional description: Atypical pneumonia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Bronchitis | Additional description: Bronchitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Bronchopulmonary aspergillosis | Additional description: Bronchopulmonary aspergillosis | | |

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|---|--|-----------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Cerebral aspergillosis | Additional description: Cerebral aspergillosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Cellulitis | Additional description: Cellulitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chronic sinusitis | Additional description: Chronic sinusitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Corona virus infection | Additional description: Corona virus infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Coronavirus infection | Additional description: Coronavirus infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 3 / 216 (1.39%) | 0 / 237 (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 |
| COVID-19 | Additional description: COVID-19 | | |
| subjects affected / exposed | 13 / 228 (5.70%) | 6 / 216 (2.78%) | 13 / 237 (5.49%) |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 6 | 0 / 14 |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | 0 / 0 |
| COVID-19 pneumonia | Additional description: COVID-19 pneumonia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 3 / 237 (1.27%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cryptococcal fungaemia | Additional description: Cryptococcal fungaemia | | |

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|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Cystitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Cytomegalovirus infection | Additional description: Cytomegalovirus infection | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytomegalovirus infection reactivation | Additional description: Cytomegalovirus infection reactivation | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Diverticulitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Encephalitis fungal | Additional description: Encephalitis fungal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocarditis | Additional description: Endocarditis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Erysipelas | Additional description: Erysipelas | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 4 / 216 (1.85%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 3 | 2 / 4 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epididymitis | Additional description: Epididymitis | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 3 / 228 (1.32%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 2 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epstein-Barr virus infection | Additional description: Epstein-Barr virus infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Enterocolitis infectious | Additional description: Enterocolitis infectious | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia urinary tract infection | Additional description: Escherichia urinary tract infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| 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 | Additional description: Febrile infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 5 / 216 (2.31%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 5 / 5 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | Additional description: Escherichia bacteraemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Gallbladder empyema | Additional description: Gallbladder empyema | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | Additional description: Gastroenteritis | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal infection | Additional description: Gastrointestinal infection | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Genital herpes zoster | Additional description: Genital herpes zoster | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Giardiasis | Additional description: Giardiasis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 B | Additional description: Hepatitis B | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis B reactivation | Additional description: Hepatitis B reactivation | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Hepatitis E | Additional description: Hepatitis E | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Herpes zoster | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 8 / 216 (3.70%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 4 / 8 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes zoster meningoencephalitis | Additional description: Herpes zoster meningoencephalitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Herpes zoster reactivation | Additional description: Herpes zoster reactivation | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Impetigo | Additional description: Impetigo | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Infected seroma | Additional description: Infected seroma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infection | Additional description: Infection | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 5 / 216 (2.31%) | 6 / 237 (2.53%) |
| occurrences causally related to treatment / all | 2 / 3 | 3 / 6 | 0 / 6 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious pleural effusion | Additional description: Infectious pleural effusion | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infective exacerbation of chronic obstructive airways disease | Additional description: Infective exacerbation of chronic obstructive airways disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | Additional description: Influenza | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 7 / 216 (3.24%) | 7 / 237 (2.95%) |
| occurrences causally related to treatment / all | 0 / 2 | 2 / 7 | 2 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Keratitis bacterial | Additional description: Keratitis bacterial | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Kidney infection | Additional description: Kidney infection | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laryngitis | Additional description: Laryngitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | Additional description: Lower respiratory tract infection | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Lung infection | Additional description: Lung infection | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lyme disease | Additional description: Lyme disease | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymph gland infection | Additional description: Lymph gland infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Localised infection | Additional description: Localised infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Meningitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Meningitis viral | Additional description: Meningitis viral | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Mycoplasma infection | Additional description: Mycoplasma infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Neutropenic infection | Additional description: Neutropenic infection | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myelitis | Additional description: Myelitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Osteomyelitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pelvic abscess | Additional description: Pelvic abscess | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| 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 | Additional description: Pharyngitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Papilloma viral infection | Additional description: Papilloma viral infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Parainfluenzae virus infection | Additional description: Parainfluenzae virus infection | | |

| | | | |
|---|--|------------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural infection | Additional description: Pleural infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumocystis jirovecii pneumonia | Additional description: Pneumocystis jirovecii pneumonia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 3 / 216 (1.39%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | Additional description: Pneumonia | | |
| subjects affected / exposed | 17 / 228 (7.46%) | 18 / 216 (8.33%) | 17 / 237 (7.17%) |
| occurrences causally related to treatment / all | 12 / 25 | 12 / 24 | 4 / 19 |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| Pneumonia adenoviral | Additional description: Pneumonia adenoviral | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 influenzal | Additional description: Pneumonia influenzal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia legionella | Additional description: Pneumonia legionella | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 mycoplasmal | Additional description: Pneumonia mycoplasmal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 pneumococcal | Additional description: Pneumonia pneumococcal | | |

| | | | |
|---|---|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 staphylococcal | Additional description: Pneumonia staphylococcal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia streptococcal | Additional description: Pneumonia streptococcal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia fungal | Additional description: Pneumonia fungal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pseudomonas infection | Additional description: Pseudomonas infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal abscess | Additional description: Rectal abscess | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | Additional description: Respiratory syncytial virus infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection | Additional description: Respiratory tract infection | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sialoadenitis | Additional description: Sialoadenitis | | |

| | | | |
|---|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Sepsis | Additional description: Sepsis | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 3 / 216 (1.39%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 3 | 2 / 3 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| Septic shock | Additional description: Septic shock | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Sinobronchitis | Additional description: Sinobronchitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 infection | Additional description: Skin infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | Additional description: Sinusitis | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal infection | Additional description: Staphylococcal infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal infection | Additional description: Streptococcal infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal sepsis | Additional description: Streptococcal sepsis | | |

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|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (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 |
| Subcutaneous abscess | Additional description: Subcutaneous abscess | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Suspected COVID-19 | Additional description: Suspected COVID-19 | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal sepsis | Additional description: Staphylococcal sepsis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| 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 | Additional description: Tooth abscess | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Tooth infection | Additional description: Tooth infection | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | Additional description: Upper respiratory tract infection | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 3 / 237 (1.27%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 2 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | Additional description: Viral infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vestibular neuronitis | Additional description: Vestibular neuronitis | | |

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|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | Additional description: Urinary tract infection | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 4 / 216 (1.85%) | 6 / 237 (2.53%) |
| occurrences causally related to treatment / all | 1 / 5 | 2 / 4 | 5 / 7 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | Additional description: Dehydration | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperphosphataemia | Additional description: Hyperphosphataemia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 4 / 237 (1.69%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | 5 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperglycaemia | Additional description: Hyperglycaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperkalaemia | Additional description: Hyperkalaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | Additional description: Hyponatraemia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperuricaemia | Additional description: Hyperuricaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 3 / 237 (1.27%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 3 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | Additional description: Hypoglycaemia | | |

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|---|---|-----------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (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 |
| Hypokalaemia | Additional description: Hypokalaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypophosphataemia | Additional description: Hypophosphataemia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (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 |
| Tumour lysis syndrome | Additional description: Tumour lysis syndrome | | |
| subjects affected / exposed | 9 / 228 (3.95%) | 4 / 216 (1.85%) | 11 / 237 (4.64%) |
| occurrences causally related to treatment / all | 9 / 9 | 4 / 4 | 12 / 12 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|--|--|
| Serious adverse events | GIVe arm | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 146 / 231 (63.20%) | | |
| number of deaths (all causes) | 13 | | |
| number of deaths resulting from adverse events | 13 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute myeloid leukaemia | Additional description: Acute myeloid leukaemia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Adenocarcinoma pancreas | Additional description: Adenocarcinoma pancreas | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Basal cell carcinoma | Additional description: Basal cell carcinoma | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences causally related to treatment / all | 3 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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|----------------------------------|--|-----------------|--|
| Bladder cancer | Additional description: Bladder cancer | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Bowen's disease | Additional description: Bowen's disease | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Breast cancer | Additional description: Breast cancer | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Chondrosarcoma | Additional description: Chondrosarcoma | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Central nervous system leukaemia | Additional description: Central nervous system leukaemia | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Colon cancer | Additional description: Colon cancer | | |
| | subjects affected / exposed | 1 / 231 (0.43%) | |
| | occurrences causally related to treatment / all | 1 / 1 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Dedifferentiated liposarcoma | Additional description: Dedifferentiated liposarcoma | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Follicular lymphoma | Additional description: Follicular lymphoma | | |
| | subjects affected / exposed | 1 / 231 (0.43%) | |
| | occurrences causally related to treatment / all | 0 / 1 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Glioblastoma | Additional description: Glioblastoma | | |
| | | | |

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|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Hepatocellular carcinoma | Additional description: Hepatocellular carcinoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypopharyngeal cancer | Additional description: Hypopharyngeal cancer | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lipoma | Additional description: Lipoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malignant neoplasm of unknown primary site | Additional description: Malignant neoplasm of unknown primary site | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung adenocarcinoma | Additional description: Lung adenocarcinoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung neoplasm malignant | Additional description: Lung neoplasm malignant | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malignant melanoma | Additional description: Malignant melanoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Mantle cell lymphoma | Additional description: Mantle cell lymphoma | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Meningioma | Additional description: Meningioma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Meningioma benign | Additional description: Meningioma benign | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metastatic gastric cancer | Additional description: Metastatic gastric cancer | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myelodysplastic syndrome | Additional description: Myelodysplastic syndrome | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myxoid liposarcoma | Additional description: Myxoid liposarcoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Non-small cell lung cancer | Additional description: Non-small cell lung cancer | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oesophageal adenocarcinoma | Additional description: Oesophageal adenocarcinoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Oesophageal carcinoma | Additional description: Oesophageal carcinoma | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ovarian adenoma | Additional description: Ovarian adenoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Phaeochromocytoma | Additional description: Phaeochromocytoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Plasma cell myeloma | Additional description: Plasma cell myeloma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Papillary thyroid cancer | Additional description: Papillary thyroid cancer | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Polycythaemia vera | Additional description: Polycythaemia vera | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Prostate cancer | Additional description: Prostate cancer | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Prostate cancer metastatic | Additional description: Prostate cancer metastatic | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rectal adenocarcinoma | Additional description: Rectal adenocarcinoma | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rectal cancer | Additional description: Rectal cancer | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal Cell Carcinoma | Additional description: Renal Cell Carcinoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Richter's syndrome | Additional description: Richter's syndrome | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Salivary gland adenoma | Additional description: Salivary gland adenoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Salivary gland cancer | Additional description: Salivary gland cancer | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Seborrhoeic keratosis | Additional description: Seborrhoeic keratosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Squamous cell carcinoma of skin | Additional description: Squamous cell carcinoma of skin | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin squamous cell carcinoma metastatic | Additional description: Skin squamous cell carcinoma metastatic | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Small cell lung cancer | Additional description: Small cell lung cancer | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Soft tissue sarcoma | Additional description: Soft tissue sarcoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal cord neoplasm | Additional description: Spinal cord neoplasm | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Squamous cell carcinoma | Additional description: Squamous cell carcinoma | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences causally related to treatment / all | 2 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Uterine leiomyoma | Additional description: Uterine leiomyoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Aortic aneurysm | Additional description: Aortic aneurysm | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Aortic stenosis | Additional description: Aortic stenosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blue toe syndrome | Additional description: Blue toe syndrome | | |

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|---|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Deep vein thrombosis | Additional description: Deep vein thrombosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertension | Additional description: Hypertension | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypertensive crisis | Additional description: Hypertensive crisis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypotension | Additional description: Hypotension | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Orthostatic hypotension | Additional description: Orthostatic hypotension | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Peripheral arterial occlusive disease | Additional description: Peripheral arterial occlusive disease | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Peripheral ischaemia | Additional description: Peripheral ischaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Polyarteritis nodosa | Additional description: Polyarteritis nodosa | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombophlebitis | Additional description: Thrombophlebitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Surgical and medical procedures | | | |
| Chest tube removal | Additional description: Chest tube removal | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholecystectomy | Additional description: Cholecystectomy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronary arterial stent insertion | Additional description: Coronary arterial stent insertion | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronary artery bypass | Additional description: Coronary artery bypass | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epidermoid cyst excision | Additional description: Epidermoid cyst excision | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ethmoid sinus surgery | Additional description: Ethmoid sinus surgery | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrectomy | Additional description: Gastrectomy | | |

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|--|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hip arthroplasty | Additional description: Hip arthroplasty | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hip surgery | Additional description: Hip surgery | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Adverse drug reaction | Additional description: Adverse drug reaction | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Asthenia | Additional description: Asthenia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Chest pain | Additional description: Chest pain | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Death | Additional description: Death | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Fatigue | Additional description: Fatigue | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General physical health deterioration | Additional description: General physical health deterioration | | |

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|---|---|--|--|
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Influenza like illness | Additional description: Influenza like illness | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malaise | Additional description: Malaise | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oedema peripheral | Additional description: Oedema peripheral | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Puncture site haematoma | Additional description: Puncture site haematoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pyrexia | Additional description: Pyrexia | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences causally related to treatment / all | 4 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Immune system disorders | | | |
| Anaphylactic reaction | Additional description: Anaphylactic reaction | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cytokine release syndrome | Additional description: Cytokine release syndrome | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Drug hypersensitivity | Additional description: Drug hypersensitivity | | |

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|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypersensitivity | Additional description: Hypersensitivity | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sarcoidosis | Additional description: Sarcoidosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | Additional description: Benign prostatic hyperplasia | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Genital prolapse | Additional description: Genital prolapse | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Menorrhagia | Additional description: Menorrhagia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rectocele | Additional description: Rectocele | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchial obstruction | Additional description: Bronchial obstruction | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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|----------------------------|--|-----------------|--|
| Bronchitis chronic | Additional description: Bronchitis chronic | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Dyspnoea | Additional description: Dyspnoea | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Nasal septum disorder | Additional description: Nasal septum disorder | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Obliterative bronchiolitis | Additional description: Obliterative bronchiolitis | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Pleural effusion | Additional description: Pleural effusion | | |
| | subjects affected / exposed | 1 / 231 (0.43%) | |
| | occurrences causally related to treatment / all | 0 / 1 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Pleuritic pain | Additional description: Pleuritic pain | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Pneumonitis | Additional description: Pneumonitis | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Pneumothorax | Additional description: Pneumothorax | | |
| | subjects affected / exposed | 2 / 231 (0.87%) | |
| | occurrences causally related to treatment / all | 0 / 2 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Pulmonary embolism | Additional description: Pulmonary embolism | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary fibrosis | Additional description: Pulmonary fibrosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary mass | Additional description: Pulmonary mass | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory failure | Additional description: Respiratory failure | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Upper-airway cough syndrome | Additional description: Upper-airway cough syndrome | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Completed suicide | Additional description: Completed suicide | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Delirium | Additional description: Delirium | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Depression | Additional description: Depression | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Insomnia | Additional description: Insomnia | | |

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|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Suicide attempt | Additional description: Suicide attempt | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Investigations | | | |
| Blood lactate dehydrogenase increased | Additional description: Blood lactate dehydrogenase increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood creatine increased | Additional description: Blood creatine increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood creatine phosphokinase increased | Additional description: Blood creatine phosphokinase increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood creatinine increased | Additional description: Blood creatinine increased | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences causally related to treatment / all | 2 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood phosphorus increased | Additional description: Blood phosphorus increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood potassium increased | Additional description: Blood potassium increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatic enzyme increased | Additional description: Hepatic enzyme increased | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Medical observation | Additional description: Medical observation | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myocardial necrosis marker increased | Additional description: Myocardial necrosis marker increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| N-terminal prohormone brain natriuretic peptide increased | Additional description: N-terminal prohormone brain natriuretic peptide increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Prostatic specific antigen increased | Additional description: Prostatic specific antigen increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| SARS-CoV-2 test positive | Additional description: SARS-CoV-2 test positive | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Transaminases increased | Additional description: Transaminases increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Alcohol poisoning | Additional description: Alcohol poisoning | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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|-----------------------|---|-----------------|--|
| Ankle fracture | Additional description: Ankle fracture | | |
| | subjects affected / exposed | 1 / 231 (0.43%) | |
| | occurrences causally related to treatment / all | 0 / 1 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Forearm fracture | Additional description: Forearm fracture | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Facial bones fracture | Additional description: Facial bones fracture | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Fall | Additional description: Fall | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Femoral neck fracture | Additional description: Femoral neck fracture | | |
| | subjects affected / exposed | 1 / 231 (0.43%) | |
| | occurrences causally related to treatment / all | 0 / 1 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Femur fracture | Additional description: Femur fracture | | |
| | subjects affected / exposed | 1 / 231 (0.43%) | |
| | occurrences causally related to treatment / all | 0 / 1 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Fibula fracture | Additional description: Fibula fracture | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Foot fracture | Additional description: Foot fracture | | |
| | subjects affected / exposed | 0 / 231 (0.00%) | |
| | occurrences causally related to treatment / all | 0 / 0 | |
| | deaths causally related to treatment / all | 0 / 0 | |
| Hand fracture | Additional description: Hand fracture | | |
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|---|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hip fracture | Additional description: Hip fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Humerus fracture | Additional description: Humerus fracture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infusion related reaction | Additional description: Infusion related reaction | | |
| subjects affected / exposed | 11 / 231 (4.76%) | | |
| occurrences causally related to treatment / all | 10 / 11 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Kidney rupture | Additional description: Kidney rupture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lumbar vertebral fracture | Additional description: Lumbar vertebral fracture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Multiple fractures | Additional description: Multiple fractures | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Multiple injuries | Additional description: Multiple injuries | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Meniscus injury | Additional description: Meniscus injury | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Post procedural haematoma | Additional description: Post procedural haematoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Procedural intestinal perforation | Additional description: Procedural intestinal perforation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reactive gastropathy | Additional description: Reactive gastropathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Silicosis | Additional description: Silicosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Road traffic accident | Additional description: Road traffic accident | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skull fracture | Additional description: Skull fracture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal compression fracture | Additional description: Spinal compression fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal fracture | Additional description: Spinal fracture | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thermal burn | Additional description: Thermal burn | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Subdural haematoma | Additional description: Subdural haematoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thoracic vertebral fracture | Additional description: Thoracic vertebral fracture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tibia fracture | Additional description: Tibia fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ulna fracture | Additional description: Ulna fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Wrist fracture | Additional description: Wrist fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Congenital, familial and genetic disorders | | | |
| Adenomatous polyposis coli | Additional description: Adenomatous polyposis coli | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |

| | | | |
|--|--|--|--|
| Acute coronary syndrome subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Acute coronary syndrome | | |
| | 0 / 231 (0.00%) | | |
| | 0 / 0 | | |
| | 0 / 0 | | |
| Acute myocardial infarction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Acute myocardial infarction | | |
| | 3 / 231 (1.30%) | | |
| | 1 / 3 | | |
| | 0 / 0 | | |
| Atrial tachycardia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Atrial tachycardia | | |
| | 1 / 231 (0.43%) | | |
| | 0 / 1 | | |
| | 0 / 0 | | |
| Aortic valve disease subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Aortic valve disease | | |
| | 1 / 231 (0.43%) | | |
| | 0 / 1 | | |
| | 0 / 0 | | |
| Arteriosclerosis coronary artery subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Arteriosclerosis coronary artery | | |
| | 0 / 231 (0.00%) | | |
| | 0 / 0 | | |
| | 0 / 0 | | |
| Atrial fibrillation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Atrial fibrillation | | |
| | 6 / 231 (2.60%) | | |
| | 4 / 7 | | |
| | 0 / 0 | | |
| Atrial flutter subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Atrial flutter | | |
| | 0 / 231 (0.00%) | | |
| | 0 / 0 | | |
| | 0 / 0 | | |
| Angina pectoris subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | Additional description: Angina pectoris | | |
| | 1 / 231 (0.43%) | | |
| | 1 / 1 | | |
| | 0 / 0 | | |
| Atrioventricular block | Additional description: Atrioventricular block | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac arrest | Additional description: Cardiac arrest | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure | Additional description: Cardiac failure | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure congestive | Additional description: Cardiac failure congestive | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiomyopathy | Additional description: Cardiomyopathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronary artery disease | Additional description: Coronary artery disease | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Intracardiac thrombus | Additional description: Intracardiac thrombus | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myocardial infarction | Additional description: Myocardial infarction | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myocarditis | Additional description: Myocarditis | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pericarditis | Additional description: Pericarditis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Palpitations | Additional description: Palpitations | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pericardial effusion | Additional description: Pericardial effusion | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sinus node dysfunction | Additional description: Sinus node dysfunction | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Stress cardiomyopathy | Additional description: Stress cardiomyopathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Supraventricular tachycardia | Additional description: Supraventricular tachycardia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ventricular fibrillation | Additional description: Ventricular fibrillation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Carotid artery stenosis | Additional description: Carotid artery stenosis | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Carotid artery occlusion | Additional description: Carotid artery occlusion | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebellar stroke | Additional description: Cerebellar stroke | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebral haemorrhage | Additional description: Cerebral haemorrhage | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebral ischaemia | Additional description: Cerebral ischaemia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebrovascular accident | Additional description: Cerebrovascular accident | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dysaesthesia | Additional description: Dysaesthesia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dizziness | Additional description: Dizziness | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Embolic cerebral infarction | Additional description: Embolic cerebral infarction | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Encephalitis autoimmune | Additional description: Encephalitis autoimmune | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epilepsy | Additional description: Epilepsy | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemorrhagic stroke | Additional description: Haemorrhagic stroke | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Headache | Additional description: Headache | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ischaemic stroke | Additional description: Ischaemic stroke | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myasthenia gravis | Additional description: Myasthenia gravis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Polyneuropathy | Additional description: Polyneuropathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Seizure | Additional description: Seizure | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Syncope | Additional description: Syncope | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombotic stroke | Additional description: Thrombotic stroke | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Toxic leukoencephalopathy | Additional description: Toxic leukoencephalopathy | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Transient global amnesia | Additional description: Transient global amnesia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Transient ischaemic attack | Additional description: Transient ischaemic attack | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vocal cord paresis | Additional description: Vocal cord paresis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | Additional description: Anaemia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Aplasia pure red cell | Additional description: Aplasia pure red cell | | |

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|---|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Autoimmune haemolytic anaemia | Additional description: Autoimmune haemolytic anaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Autoimmune neutropenia | Additional description: Autoimmune neutropenia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Febrile neutropenia | Additional description: Febrile neutropenia | | |
| subjects affected / exposed | 17 / 231 (7.36%) | | |
| occurrences causally related to treatment / all | 17 / 18 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemolytic anaemia | Additional description: Haemolytic anaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Immune thrombocytopenia | Additional description: Immune thrombocytopenia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Leukostasis syndrome | Additional description: Leukostasis syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lymphadenitis | Additional description: Lymphadenitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lymphocytosis | Additional description: Lymphocytosis | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neutropenia | Additional description: Neutropenia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancytopenia | Additional description: Pancytopenia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Splenomegaly | Additional description: Splenomegaly | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia | Additional description: Thrombocytopenia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ear and labyrinth disorders | | | |
| Vertigo | Additional description: Vertigo | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vertigo positional | Additional description: Vertigo positional | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Acute macular outer retinopathy | Additional description: Acute macular outer retinopathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cataract | Additional description: Cataract | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dacryostenosis acquired | Additional description: Dacryostenosis acquired | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eyelid cyst | Additional description: Eyelid cyst | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Macular hole | Additional description: Macular hole | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Optic ischaemic neuropathy | Additional description: Optic ischaemic neuropathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Retinal detachment | Additional description: Retinal detachment | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Venous stasis retinopathy | Additional description: Venous stasis retinopathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain | Additional description: Abdominal pain | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal hernia | Additional description: Abdominal hernia | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain upper | Additional description: Abdominal pain upper | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diarrhoea | Additional description: Diarrhoea | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences causally related to treatment / all | 5 / 6 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diverticulum intestinal | Additional description: Diverticulum intestinal | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Duodenal perforation | Additional description: Duodenal perforation | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Duodenal ulcer haemorrhage | Additional description: Duodenal ulcer haemorrhage | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Enlarged uvula | Additional description: Enlarged uvula | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epiploic appendagitis | Additional description: Epiploic appendagitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Erosive oesophagitis | Additional description: Erosive oesophagitis | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastritis | Additional description: Gastritis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastritis erosive | Additional description: Gastritis erosive | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal haemorrhage | Additional description: Gastrointestinal haemorrhage | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrooesophageal reflux disease | Additional description: Gastrooesophageal reflux disease | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemorrhagic erosive gastritis | Additional description: Haemorrhagic erosive gastritis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ileus | Additional description: Ileus | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Impaired gastric emptying | Additional description: Impaired gastric emptying | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Inguinal hernia | Additional description: Inguinal hernia | | |

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|---|--|--|--|
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Irritable bowel syndrome | Additional description: Irritable bowel syndrome | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nausea | Additional description: Nausea | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oesophageal rupture | Additional description: Oesophageal rupture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatitis | Additional description: Pancreatitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pancreatolithiasis | Additional description: Pancreatolithiasis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Stomatitis | Additional description: Stomatitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Upper gastrointestinal haemorrhage | Additional description: Upper gastrointestinal haemorrhage | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Bile duct stenosis | Additional description: Bile duct stenosis | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Biliary colic | Additional description: Biliary colic | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholecystitis | Additional description: Cholecystitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholecystitis acute | Additional description: Cholecystitis acute | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholelithiasis | Additional description: Cholelithiasis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gallbladder polyp | Additional description: Gallbladder polyp | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatotoxicity | Additional description: Hepatotoxicity | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Liver disorder | Additional description: Liver disorder | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Subcapsular hepatic haematoma | Additional description: Subcapsular hepatic haematoma | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Actinic keratosis | Additional description: Actinic keratosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dermatitis allergic | | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Erythema multiforme | | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rash | | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | Additional description: Acute kidney injury | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nephrolithiasis | | | |
| | Additional description: Nephrolithiasis | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal colic | Additional description: Renal colic | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ureterolithiasis | Additional description: Ureterolithiasis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urethral caruncle | Additional description: Urethral caruncle | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urethral stenosis | Additional description: Urethral stenosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary retention | Additional description: Urinary retention | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Endocrine disorders | | | |
| Goitre | Additional description: Goitre | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperthyroidism | Additional description: Hyperthyroidism | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|--|--|--|
| Arthralgia | Additional description: Arthralgia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Back pain | Additional description: Back pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bursitis | Additional description: Bursitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dupuytren's contracture | Additional description: Dupuytren's contracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gouty arthritis | Additional description: Gouty arthritis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemarthrosis | Additional description: Haemarthrosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haematoma muscle | Additional description: Haematoma muscle | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypercreatinaemia | Additional description: Hypercreatinaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Intervertebral disc protrusion | Additional description: Intervertebral disc protrusion | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal pain | Additional description: Musculoskeletal pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pain in extremity | Additional description: Pain in extremity | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Osteochondrosis | Additional description: Osteochondrosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Osteonecrosis | Additional description: Osteonecrosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Osteoporotic fracture | Additional description: Osteoporotic fracture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Osteoarthritis | Additional description: Osteoarthritis | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Periarthritis | Additional description: Periarthritis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Polymyalgia rheumatica | Additional description: Polymyalgia rheumatica | | |

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|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rotator cuff syndrome | Additional description: Rotator cuff syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Scleroderma | Additional description: Scleroderma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal column stenosis | Additional description: Spinal column stenosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Spinal pain | Additional description: Spinal pain | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tenosynovitis | Additional description: Tenosynovitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Anal abscess | Additional description: Anal abscess | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abscess limb | Additional description: Abscess limb | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abscess | Additional description: Abscess | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Appendicitis | Additional description: Appendicitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Appendicitis perforated | Additional description: Appendicitis perforated | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Asymptomatic COVID-19 | Additional description: Asymptomatic COVID-19 | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bacteraemia | Additional description: Bacteraemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bacterial infection | Additional description: Bacterial infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atypical pneumonia | Additional description: Atypical pneumonia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis | Additional description: Bronchitis | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences causally related to treatment / all | 2 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchopulmonary aspergillosis | Additional description: Bronchopulmonary aspergillosis | | |

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|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebral aspergillosis | Additional description: Cerebral aspergillosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cellulitis | Additional description: Cellulitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Chronic sinusitis | Additional description: Chronic sinusitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Corona virus infection | Additional description: Corona virus infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Coronavirus infection | Additional description: Coronavirus infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| COVID-19 | Additional description: COVID-19 | | |
| subjects affected / exposed | 8 / 231 (3.46%) | | |
| occurrences causally related to treatment / all | 0 / 8 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| COVID-19 pneumonia | Additional description: COVID-19 pneumonia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cryptococcal fungaemia | Additional description: Cryptococcal fungaemia | | |

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|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cystitis | Additional description: Cystitis | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cytomegalovirus infection | Additional description: Cytomegalovirus infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cytomegalovirus infection reactivation | Additional description: Cytomegalovirus infection reactivation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diverticulitis | Additional description: Diverticulitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Encephalitis fungal | Additional description: Encephalitis fungal | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Endocarditis | Additional description: Endocarditis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Erysipelas | Additional description: Erysipelas | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epididymitis | Additional description: Epididymitis | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Epstein-Barr virus infection | Additional description: Epstein-Barr virus infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Enterocolitis infectious | Additional description: Enterocolitis infectious | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Escherichia urinary tract infection | Additional description: Escherichia urinary tract infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Febrile infection | Additional description: Febrile infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Escherichia bacteraemia | Additional description: Escherichia bacteraemia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gallbladder empyema | Additional description: Gallbladder empyema | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastroenteritis | Additional description: Gastroenteritis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal infection | Additional description: Gastrointestinal infection | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Genital herpes zoster | Additional description: Genital herpes zoster | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Giardiasis | Additional description: Giardiasis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatitis B | Additional description: Hepatitis B | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatitis B reactivation | Additional description: Hepatitis B reactivation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatitis E | Additional description: Hepatitis E | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Herpes zoster | Additional description: Herpes zoster | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Herpes zoster meningoencephalitis | Additional description: Herpes zoster meningoencephalitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Herpes zoster reactivation | Additional description: Herpes zoster reactivation | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Impetigo | Additional description: Impetigo | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infected seroma | Additional description: Infected seroma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infection | Additional description: Infection | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences causally related to treatment / all | 3 / 6 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infectious pleural effusion | Additional description: Infectious pleural effusion | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infective exacerbation of chronic obstructive airways disease | Additional description: Infective exacerbation of chronic obstructive airways disease | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Influenza | Additional description: Influenza | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Keratitis bacterial | Additional description: Keratitis bacterial | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Kidney infection | Additional description: Kidney infection | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Laryngitis | Additional description: Laryngitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lower respiratory tract infection | Additional description: Lower respiratory tract infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lung infection | Additional description: Lung infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lyme disease | Additional description: Lyme disease | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lymph gland infection | Additional description: Lymph gland infection | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Localised infection | Additional description: Localised infection | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Meningitis | Additional description: Meningitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Meningitis viral | Additional description: Meningitis viral | | |

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|---|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Mycoplasma infection | Additional description: Mycoplasma infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neutropenic infection | Additional description: Neutropenic infection | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Myelitis | Additional description: Myelitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Osteomyelitis | Additional description: Osteomyelitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pelvic abscess | Additional description: Pelvic abscess | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pharyngitis | Additional description: Pharyngitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Papilloma viral infection | Additional description: Papilloma viral infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Parainfluenzae virus infection | Additional description: Parainfluenzae virus infection | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pleural infection | Additional description: Pleural infection | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumocystis jirovecii pneumonia | Additional description: Pneumocystis jirovecii pneumonia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia | Additional description: Pneumonia | | |
| subjects affected / exposed | 19 / 231 (8.23%) | | |
| occurrences causally related to treatment / all | 14 / 22 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia adenoviral | Additional description: Pneumonia adenoviral | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia influenzal | Additional description: Pneumonia influenzal | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia legionella | Additional description: Pneumonia legionella | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia mycoplasmal | Additional description: Pneumonia mycoplasmal | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia pneumococcal | Additional description: Pneumonia pneumococcal | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia staphylococcal | Additional description: Pneumonia staphylococcal | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia streptococcal | Additional description: Pneumonia streptococcal | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences causally related to treatment / all | 1 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pneumonia fungal | Additional description: Pneumonia fungal | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pseudomonas infection | Additional description: Pseudomonas infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rectal abscess | Additional description: Rectal abscess | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory syncytial virus infection | Additional description: Respiratory syncytial virus infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory tract infection | Additional description: Respiratory tract infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sialoadenitis | Additional description: Sialoadenitis | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sepsis | Additional description: Sepsis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Septic shock | Additional description: Septic shock | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sinobronchitis | Additional description: Sinobronchitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin infection | Additional description: Skin infection | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sinusitis | Additional description: Sinusitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Staphylococcal infection | Additional description: Staphylococcal infection | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Streptococcal infection | Additional description: Streptococcal infection | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Streptococcal sepsis | Additional description: Streptococcal sepsis | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Subcutaneous abscess | Additional description: Subcutaneous abscess | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Suspected COVID-19 | Additional description: Suspected COVID-19 | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Staphylococcal sepsis | Additional description: Staphylococcal sepsis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tooth abscess | Additional description: Tooth abscess | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tooth infection | Additional description: Tooth infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Upper respiratory tract infection | Additional description: Upper respiratory tract infection | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences causally related to treatment / all | 0 / 4 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Viral infection | Additional description: Viral infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vestibular neuronitis | Additional description: Vestibular neuronitis | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | Additional description: Urinary tract infection | | |
| subjects affected / exposed | 7 / 231 (3.03%) | | |
| occurrences causally related to treatment / all | 4 / 9 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Dehydration | Additional description: Dehydration | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperphosphataemia | Additional description: Hyperphosphataemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperglycaemia | Additional description: Hyperglycaemia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperkalaemia | Additional description: Hyperkalaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyponatraemia | Additional description: Hyponatraemia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperuricaemia | Additional description: Hyperuricaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoglycaemia | Additional description: Hypoglycaemia | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypokalaemia | Additional description: Hypokalaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypophosphataemia | Additional description: Hypophosphataemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences causally related to treatment / all | 2 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tumour lysis syndrome | Additional description: Tumour lysis syndrome | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences causally related to treatment / all | 6 / 6 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | GVe arm | SCIT arm | RVe arm |
|---|---|--------------------|--------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 224 / 228 (98.25%) | 214 / 216 (99.07%) | 233 / 237 (98.31%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma of colon | Additional description: Adenocarcinoma of colon | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anogenital warts | Additional description: Anogenital warts | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Angiomyolipoma | Additional description: Angiomyolipoma | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Basal cell carcinoma | Additional description: Basal cell carcinoma | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 15 / 216 (6.94%) | 11 / 237 (4.64%) |
| occurrences (all) | 5 | 19 | 14 |

| | | | |
|---|---|----------------------|----------------------|
| Benign soft tissue neoplasm subjects affected / exposed occurrences (all) | Additional description: Benign soft tissue neoplasm | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Bowen's disease subjects affected / exposed occurrences (all) | Additional description: Bowen's disease | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 2 | 1 / 237 (0.42%) 1 |
| Choroid melanoma subjects affected / exposed occurrences (all) | Additional description: Choroid melanoma | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Colon adenoma subjects affected / exposed occurrences (all) | Additional description: Colon adenoma | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Colon cancer subjects affected / exposed occurrences (all) | Additional description: Colon cancer | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 2 / 237 (0.84%) 2 |
| Cutaneous T-cell lymphoma subjects affected / exposed occurrences (all) | Additional description: Cutaneous T-cell lymphoma | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Erythroplasia subjects affected / exposed occurrences (all) | Additional description: Erythroplasia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Fibroma subjects affected / exposed occurrences (all) | Additional description: Fibroma | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Haemangioma subjects affected / exposed occurrences (all) | Additional description: Haemangioma | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 2 / 237 (0.84%) 2 |
| Haemangioma of liver subjects affected / exposed occurrences (all) | Additional description: Haemangioma of liver | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Keratoacanthoma subjects affected / exposed occurrences (all) | Additional description: Keratoacanthoma | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Lipoma subjects affected / exposed occurrences (all) | Additional description: Lipoma | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

| | | | |
|--|--|----------------------|----------------------|
| Malignant melanoma subjects affected / exposed occurrences (all) | Additional description: Malignant melanoma | | |
| | 3 / 228 (1.32%) 4 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Melanocytic naevus subjects affected / exposed occurrences (all) | Additional description: Melanocytic naevus | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Malignant melanoma in situ subjects affected / exposed occurrences (all) | Additional description: Malignant melanoma in situ | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Myelodysplastic syndrome subjects affected / exposed occurrences (all) | Additional description: Myelodysplastic syndrome | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Myelofibrosis subjects affected / exposed occurrences (all) | Additional description: Myelofibrosis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Non-small cell lung cancer subjects affected / exposed occurrences (all) | Additional description: Non-small cell lung cancer | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Papilloma subjects affected / exposed occurrences (all) | Additional description: Papilloma | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Plasmacytoma subjects affected / exposed occurrences (all) | Additional description: Plasmacytoma | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Polycythaemia vera subjects affected / exposed occurrences (all) | Additional description: Polycythaemia vera | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Prostate cancer subjects affected / exposed occurrences (all) | Additional description: Prostate cancer | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Schwannoma subjects affected / exposed occurrences (all) | Additional description: Schwannoma | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Seborrhoeic keratosis subjects affected / exposed occurrences (all) | Additional description: Seborrhoeic keratosis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

| | | | |
|---|---|-----------------|-----------------|
| Richter's syndrome subjects affected / exposed occurrences (all) Skin papilloma subjects affected / exposed occurrences (all) Squamous cell carcinoma subjects affected / exposed occurrences (all) T-cell lymphoma subjects affected / exposed occurrences (all) Thyroid neoplasm subjects affected / exposed occurrences (all) Transitional cell carcinoma subjects affected / exposed occurrences (all) | Additional description: Richter's syndrome | | |
| | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| | 1 | 1 | 1 |
| | Additional description: Skin papilloma | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 3 / 237 (1.27%) |
| | 1 | 0 | 3 |
| | Additional description: Squamous cell carcinoma | | |
| | 3 / 228 (1.32%) | 5 / 216 (2.31%) | 1 / 237 (0.42%) |
| | 3 | 7 | 1 |
| | Additional description: T-cell lymphoma | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| | Additional description: Thyroid neoplasm | | |
| | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| | 0 | 1 | 0 |
| | Additional description: Transitional cell carcinoma | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| Vascular disorders Aortic aneurysm subjects affected / exposed occurrences (all) Aortic dilatation subjects affected / exposed occurrences (all) Arteriosclerosis subjects affected / exposed occurrences (all) Blood pressure fluctuation subjects affected / exposed occurrences (all) Blue toe syndrome subjects affected / exposed occurrences (all) Circulatory collapse | | | |
| | Additional description: Aortic aneurysm | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| | Additional description: Aortic dilatation | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 1 | 0 | 0 |
| | Additional description: Arteriosclerosis | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| | Additional description: Blood pressure fluctuation | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| | Additional description: Blue toe syndrome | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| | Additional description: Circulatory collapse | | |

| | | | |
|---------------------------------------|---|------------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Deep vein thrombosis | Additional description: Deep vein thrombosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Embolism | Additional description: Embolism | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 1 | 1 |
| Flushing | Additional description: Flushing | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 1 | 1 |
| Gestational hypertension | Additional description: Gestational hypertension | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematoma | Additional description: Haematoma | | |
| subjects affected / exposed | 9 / 228 (3.95%) | 4 / 216 (1.85%) | 4 / 237 (1.69%) |
| occurrences (all) | 9 | 5 | 4 |
| Haemorrhage | Additional description: Haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Hot flush | Additional description: Hot flush | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 5 / 237 (2.11%) |
| occurrences (all) | 1 | 3 | 6 |
| Hypotension | Additional description: Hypotension | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 10 / 216 (4.63%) | 5 / 237 (2.11%) |
| occurrences (all) | 5 | 11 | 7 |
| Hypertensive crisis | Additional description: Hypertensive crisis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 1 | 0 | 3 |
| Hypertension | Additional description: Hypertension | | |
| subjects affected / exposed | 23 / 228 (10.09%) | 6 / 216 (2.78%) | 17 / 237 (7.17%) |
| occurrences (all) | 25 | 10 | 17 |
| Peripheral arterial occlusive disease | Additional description: Peripheral arterial occlusive disease | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral coldness | Additional description: Peripheral coldness | | |

| | | | |
|---------------------------------|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Phlebitis | Additional description: Phlebitis | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 4 / 216 (1.85%) | 2 / 237 (0.84%) |
| occurrences (all) | 3 | 4 | 2 |
| Poor peripheral circulation | Additional description: Poor peripheral circulation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Raynaud's phenomenon | Additional description: Raynaud's phenomenon | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Thrombophlebitis | Additional description: Thrombophlebitis | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Thrombophlebitis superficial | Additional description: Thrombophlebitis superficial | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Thrombosis | Additional description: Thrombosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Varicose vein | Additional description: Varicose vein | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Vasculitis | Additional description: Vasculitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Venous thrombosis | Additional description: Venous thrombosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Surgical and medical procedures | | | |
| Cranial remodelling therapy | Additional description: Cranial remodelling therapy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Endodontic procedure | Additional description: Endodontic procedure | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|--|---|------------------|-----------------|
| Joint irrigation subjects affected / exposed occurrences (all) | Additional description: Joint irrigation | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 1 | 0 | 0 |
| | | | |
| Mastoidectomy subjects affected / exposed occurrences (all) | Additional description: Mastoidectomy | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 1 | 0 | 0 |
| | | | |
| Polypectomy subjects affected / exposed occurrences (all) | Additional description: Polypectomy | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 1 | 0 | 1 |
| | | | |
| Tooth extraction subjects affected / exposed occurrences (all) | Additional description: Tooth extraction | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| | | | |
| General disorders and administration site conditions | | | |
| | Additional description: Axillary pain | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| | | | |
| | Additional description: Asthenia | | |
| | 5 / 228 (2.19%) | 9 / 216 (4.17%) | 2 / 237 (0.84%) |
| | 5 | 10 | 2 |
| | | | |
| | Additional description: Catheter site extravasation | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| | | | |
| | Additional description: Catheter site pain | | |
| | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| | 0 | 2 | 1 |
| | | | |
| | Additional description: Catheter site swelling | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| | | | |
| | Additional description: Chest discomfort | | |
| | 4 / 228 (1.75%) | 1 / 216 (0.46%) | 3 / 237 (1.27%) |
| | 4 | 1 | 3 |
| | | | |
| | Additional description: Chest pain | | |
| | 2 / 228 (0.88%) | 11 / 216 (5.09%) | 7 / 237 (2.95%) |
| | 3 | 11 | 7 |
| | | | |
| | Additional description: Chills | | |

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|---------------------------------------|---|-------------------|-------------------|
| subjects affected / exposed | 13 / 228 (5.70%) | 13 / 216 (6.02%) | 13 / 237 (5.49%) |
| occurrences (all) | 13 | 15 | 14 |
| Catheter site bruise | Additional description: Catheter site bruise | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cyst | Additional description: Cyst | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Drug intolerance | Additional description: Drug intolerance | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Discomfort | Additional description: Discomfort | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Extravasation | Additional description: Extravasation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Face oedema | Additional description: Face oedema | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fatigue | Additional description: Fatigue | | |
| subjects affected / exposed | 76 / 228 (33.33%) | 74 / 216 (34.26%) | 79 / 237 (33.33%) |
| occurrences (all) | 92 | 91 | 92 |
| Feeling cold | Additional description: Feeling cold | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Gait disturbance | Additional description: Gait disturbance | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Feeling hot | Additional description: Feeling hot | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| General physical health deterioration | Additional description: General physical health deterioration | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 1 | 2 |
| Inflammation | Additional description: Inflammation | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Induration | Additional description: Induration | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | Additional description: Influenza like illness | | |
| subjects affected / exposed | 26 / 228 (11.40%) | 10 / 216 (4.63%) | 11 / 237 (4.64%) |
| occurrences (all) | 32 | 11 | 12 |
| Infusion site extravasation | Additional description: Infusion site extravasation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 1 | 2 |
| Injection site pain | Additional description: Injection site pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 3 / 216 (1.39%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Injection site reaction | Additional description: Injection site reaction | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 1 | 1 |
| Injection site swelling | Additional description: Injection site swelling | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Malaise | Additional description: Malaise | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 2 / 216 (0.93%) | 6 / 237 (2.53%) |
| occurrences (all) | 6 | 4 | 6 |
| Mass | Additional description: Mass | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mucosal inflammation | Additional description: Mucosal inflammation | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 3 / 216 (1.39%) | 3 / 237 (1.27%) |
| occurrences (all) | 1 | 3 | 4 |
| Non-cardiac chest pain | Additional description: Non-cardiac chest pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 1 | 2 |
| Oedema | Additional description: Oedema | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 9 / 216 (4.17%) | 4 / 237 (1.69%) |
| occurrences (all) | 6 | 12 | 5 |
| Oedema peripheral | Additional description: Oedema peripheral | | |

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| subjects affected / exposed | 6 / 228 (2.63%) | 10 / 216 (4.63%) | 14 / 237 (5.91%) |
| occurrences (all) | 6 | 13 | 14 |
| Pain | Additional description: Pain | | |
| subjects affected / exposed | 8 / 228 (3.51%) | 4 / 216 (1.85%) | 0 / 237 (0.00%) |
| occurrences (all) | 8 | 4 | 0 |
| Papillitis | Additional description: Papillitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Peripheral oedema neonatal | Additional description: Peripheral oedema neonatal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | Additional description: Peripheral swelling | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 2 / 216 (0.93%) | 4 / 237 (1.69%) |
| occurrences (all) | 3 | 2 | 4 |
| Pyrexia | Additional description: Pyrexia | | |
| subjects affected / exposed | 52 / 228 (22.81%) | 45 / 216 (20.83%) | 30 / 237 (12.66%) |
| occurrences (all) | 70 | 67 | 32 |
| Swelling | Additional description: Swelling | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Systemic inflammatory response syndrome | Additional description: Systemic inflammatory response syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thirst | Additional description: Thirst | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tissue infiltration | Additional description: Tissue infiltration | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | Additional description: Anaphylactic reaction | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Autoimmune disorder | Additional description: Autoimmune disorder | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Cytokine release syndrome | Additional description: Cytokine release syndrome | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 1 / 216 (0.46%) | 4 / 237 (1.69%) |
| occurrences (all) | 4 | 1 | 4 |
| Drug hypersensitivity | Additional description: Drug hypersensitivity | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Hypersensitivity | Additional description: Hypersensitivity | | |
| subjects affected / exposed | 10 / 228 (4.39%) | 15 / 216 (6.94%) | 4 / 237 (1.69%) |
| occurrences (all) | 10 | 16 | 5 |
| Hypogammaglobulinaemia | Additional description: Hypogammaglobulinaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 1 | 1 |
| Immune reconstitution inflammatory syndrome | Additional description: Immune reconstitution inflammatory syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunodeficiency | Additional description: Immunodeficiency | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Seasonal allergy | Additional description: Seasonal allergy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Secondary immunodeficiency | Additional description: Secondary immunodeficiency | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 1 | 1 |
| Selective IgG subclass deficiency | Additional description: Selective IgG subclass deficiency | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | Additional description: Balanoposthitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Benign prostatic hyperplasia | Additional description: Benign prostatic hyperplasia | | |

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| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Breast induration | Additional description: Breast induration | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Breast pain | Additional description: Breast pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 1 | 2 |
| Dyspareunia | Additional description: Dyspareunia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endometriosis | Additional description: Endometriosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Erectile dysfunction | Additional description: Erectile dysfunction | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| occurrences (all) | 2 | 2 | 1 |
| Haematospermia | Additional description: Haematospermia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypomenorrhoea | Additional description: Hypomenorrhoea | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Menopausal symptoms | Additional description: Menopausal symptoms | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menorrhagia | Additional description: Menorrhagia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Menstruation irregular | Additional description: Menstruation irregular | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nipple pain | Additional description: Nipple pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Ovarian hyperfunction | Additional description: Ovarian hyperfunction | | |

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|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Penis disorder | Additional description: Penis disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | Additional description: Pelvic pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Prostatic hypoplasia | Additional description: Prostatic hypoplasia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Prostatitis | Additional description: Prostatitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Scrotal oedema | Additional description: Scrotal oedema | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Testicular disorder | Additional description: Testicular disorder | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Testicular pain | Additional description: Testicular pain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vaginal haemorrhage | Additional description: Vaginal haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vaginal discharge | Additional description: Vaginal discharge | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vulvovaginal pruritus | Additional description: Vulvovaginal pruritus | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | Additional description: Asthma | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchospasm | Additional description: Bronchospasm | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chronic obstructive pulmonary disease | Additional description: Chronic obstructive pulmonary disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 4 |
| Cough | Additional description: Cough | | |
| subjects affected / exposed | 37 / 228 (16.23%) | 25 / 216 (11.57%) | 19 / 237 (8.02%) |
| occurrences (all) | 45 | 26 | 20 |
| Dysaesthesia pharynx | Additional description: Dysaesthesia pharynx | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dysphonia | Additional description: Dysphonia | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 3 / 216 (1.39%) | 4 / 237 (1.69%) |
| occurrences (all) | 3 | 4 | 5 |
| Dyspnoea | Additional description: Dyspnoea | | |
| subjects affected / exposed | 11 / 228 (4.82%) | 14 / 216 (6.48%) | 21 / 237 (8.86%) |
| occurrences (all) | 11 | 14 | 26 |
| Dyspnoea exertional | Additional description: Dyspnoea exertional | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 3 / 216 (1.39%) | 3 / 237 (1.27%) |
| occurrences (all) | 3 | 3 | 3 |
| Epistaxis | Additional description: Epistaxis | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 3 / 216 (1.39%) | 4 / 237 (1.69%) |
| occurrences (all) | 3 | 3 | 5 |
| Haemoptysis | Additional description: Haemoptysis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hiccups | Additional description: Hiccups | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hyperventilation | Additional description: Hyperventilation | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

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| Interstitial lung disease subjects affected / exposed occurrences (all) | Additional description: Interstitial lung disease | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Laryngeal inflammation subjects affected / exposed occurrences (all) | Additional description: Laryngeal inflammation | | |
| | 1 / 228 (0.44%) 1 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Nasal congestion subjects affected / exposed occurrences (all) | Additional description: Nasal congestion | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Nasal discomfort subjects affected / exposed occurrences (all) | Additional description: Nasal discomfort | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Nasal dryness subjects affected / exposed occurrences (all) | Additional description: Nasal dryness | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Nasal inflammation subjects affected / exposed occurrences (all) | Additional description: Nasal inflammation | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Nasal obstruction subjects affected / exposed occurrences (all) | Additional description: Nasal obstruction | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Nasal ulcer subjects affected / exposed occurrences (all) | Additional description: Nasal ulcer | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | Additional description: Oropharyngeal pain | | |
| | 13 / 228 (5.70%) 14 | 8 / 216 (3.70%) 10 | 14 / 237 (5.91%) 16 |
| Pharyngeal inflammation subjects affected / exposed occurrences (all) | Additional description: Pharyngeal inflammation | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Pleural effusion subjects affected / exposed occurrences (all) | Additional description: Pleural effusion | | |
| | 1 / 228 (0.44%) 1 | 2 / 216 (0.93%) 2 | 0 / 237 (0.00%) 0 |
| Pneumonitis subjects affected / exposed occurrences (all) | Additional description: Pneumonitis | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 2 / 237 (0.84%) 2 |

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| Productive cough subjects affected / exposed occurrences (all) | Additional description: Productive cough | | |
| | 1 / 228 (0.44%) 2 | 3 / 216 (1.39%) 3 | 4 / 237 (1.69%) 4 |
| Pulmonary embolism subjects affected / exposed occurrences (all) | Additional description: Pulmonary embolism | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Pulmonary hypertension subjects affected / exposed occurrences (all) | Additional description: Pulmonary hypertension | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Pulmonary pain subjects affected / exposed occurrences (all) | Additional description: Pulmonary pain | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Rhinitis allergic subjects affected / exposed occurrences (all) | Additional description: Rhinitis allergic | | |
| | 2 / 228 (0.88%) 2 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 2 |
| Respiratory alkalosis subjects affected / exposed occurrences (all) | Additional description: Respiratory alkalosis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | Additional description: Rhinorrhoea | | |
| | 3 / 228 (1.32%) 3 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Sinus pain subjects affected / exposed occurrences (all) | Additional description: Sinus pain | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Sleep apnoea syndrome subjects affected / exposed occurrences (all) | Additional description: Sleep apnoea syndrome | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Tachypnoea subjects affected / exposed occurrences (all) | Additional description: Tachypnoea | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Throat clearing subjects affected / exposed occurrences (all) | Additional description: Throat clearing | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Throat irritation subjects affected / exposed occurrences (all) | Additional description: Throat irritation | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Throatache | Additional description: Throatache | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | Additional description: Upper-airway cough syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Wheezing | Additional description: Wheezing | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |
| Abnormal dreams | Additional description: Abnormal dreams | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Agitation | Additional description: Agitation | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 1 | 1 | 2 |
| Aggression | Additional description: Aggression | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Adjustment disorder | Additional description: Adjustment disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anxiety | Additional description: Anxiety | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 3 / 216 (1.39%) | 3 / 237 (1.27%) |
| occurrences (all) | 3 | 3 | 3 |
| Apathy | Additional description: Apathy | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bruxism | Additional description: Bruxism | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Confusional state | Additional description: Confusional state | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Depression | Additional description: Depression | | |

| | | | |
|-----------------------------|--|------------------|------------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 4 / 216 (1.85%) | 4 / 237 (1.69%) |
| occurrences (all) | 2 | 5 | 4 |
| Delirium | Additional description: Delirium | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed mood | Additional description: Depressed mood | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disorientation | Additional description: Disorientation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hallucination | Additional description: Hallucination | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperarousal | Additional description: Hyperarousal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Illusion | Additional description: Illusion | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | Additional description: Insomnia | | |
| subjects affected / exposed | 7 / 228 (3.07%) | 11 / 216 (5.09%) | 10 / 237 (4.22%) |
| occurrences (all) | 9 | 11 | 10 |
| Irritability | Additional description: Irritability | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Panic attack | Additional description: Panic attack | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 2 |
| Restlessness | Additional description: Restlessness | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Sleep disorder | Additional description: Sleep disorder | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 6 / 237 (2.53%) |
| occurrences (all) | 1 | 0 | 8 |
| Somnambulism | Additional description: Somnambulism | | |

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|---|---|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stress | Additional description: Stress | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | Additional description: Activated partial thromboplastin time prolonged | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | Additional description: Alanine aminotransferase increased | | |
| subjects affected / exposed | 15 / 228 (6.58%) | 1 / 216 (0.46%) | 3 / 237 (1.27%) |
| occurrences (all) | 16 | 1 | 3 |
| Amylase increased | Additional description: Amylase increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Aspartate aminotransferase increased | Additional description: Aspartate aminotransferase increased | | |
| subjects affected / exposed | 10 / 228 (4.39%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 10 | 0 | 0 |
| Blood immunoglobulin G decreased | Additional description: Blood immunoglobulin G decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Basophil count decreased | Additional description: Basophil count decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood alkaline phosphatase increased | Additional description: Blood alkaline phosphatase increased | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 4 | 1 | 2 |
| Blood bilirubin increased | Additional description: Blood bilirubin increased | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 0 / 216 (0.00%) | 3 / 237 (1.27%) |
| occurrences (all) | 7 | 0 | 3 |
| Blood calcium decreased | Additional description: Blood calcium decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood chloride increased | Additional description: Blood chloride increased | | |

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|---|---|-----------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood creatine increased | Additional description: Blood creatine increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood creatinine increased | Additional description: Blood creatinine increased | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 7 / 216 (3.24%) | 13 / 237 (5.49%) |
| occurrences (all) | 6 | 7 | 19 |
| Blood glucose increased | Additional description: Blood glucose increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood immunoglobulin M decreased | Additional description: Blood immunoglobulin M decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood lactate dehydrogenase increased | Additional description: Blood lactate dehydrogenase increased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 9 / 237 (3.80%) |
| occurrences (all) | 2 | 1 | 11 |
| Blood phosphorus increased | Additional description: Blood phosphorus increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 6 / 237 (2.53%) |
| occurrences (all) | 1 | 1 | 8 |
| Blood potassium decreased | Additional description: Blood potassium decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood potassium increased | Additional description: Blood potassium increased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 2 | 0 | 1 |
| Blood pressure increased | Additional description: Blood pressure increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood thyroid stimulating hormone increased | Additional description: Blood thyroid stimulating hormone increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urea increased | Additional description: Blood urea increased | | |

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|------------------------------|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood uric acid decreased | Additional description: Blood uric acid decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood uric acid increased | Additional description: Blood uric acid increased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 0 | 2 |
| Body temperature increased | Additional description: Body temperature increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood iron decreased | Additional description: Blood iron decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac murmur | Additional description: Cardiac murmur | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bronchoscopy | Additional description: Bronchoscopy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| C-reactive protein | Additional description: C-reactive protein | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| C-reactive protein increased | Additional description: C-reactive protein increased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| occurrences (all) | 3 | 2 | 2 |
| Cortisol decreased | Additional description: Cortisol decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterococcus test positive | Additional description: Enterococcus test positive | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eosinophil count decreased | Additional description: Eosinophil count decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Free haemoglobin present | Additional description: Free haemoglobin present | | |

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|---|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | Additional description: Gamma-glutamyltransferase increased | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 7 | 1 | 0 |
| Glomerular filtration rate decreased | Additional description: Glomerular filtration rate decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Heart rate irregular | Additional description: Heart rate irregular | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hepatic enzyme abnormal | Additional description: Hepatic enzyme abnormal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatic enzyme increased | Additional description: Hepatic enzyme increased | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 5 | 0 | 2 |
| Hepatitis B DNA increased | Additional description: Hepatitis B DNA increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Immunoglobulins decreased | Additional description: Immunoglobulins decreased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Inflammatory marker increased | Additional description: Inflammatory marker increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| International normalised ratio increased | Additional description: International normalised ratio increased | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intraocular pressure increased | Additional description: Intraocular pressure increased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Left ventricular end-diastolic pressure decreased | Additional description: Left ventricular end-diastolic pressure decreased | | |

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|---|---|-------------------|-------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lipase increased | Additional description: Lipase increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Liver function test increased | Additional description: Liver function test increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Monocyte count decreased | Additional description: Monocyte count decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 2 |
| Myocardial necrosis marker increased | Additional description: Myocardial necrosis marker increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| N-terminal prohormone brain natriuretic peptide increased | Additional description: N-terminal prohormone brain natriuretic peptide increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Neutrophil count decreased | Additional description: Neutrophil count decreased | | |
| subjects affected / exposed | 33 / 228 (14.47%) | 22 / 216 (10.19%) | 31 / 237 (13.08%) |
| occurrences (all) | 56 | 27 | 44 |
| Platelet count decreased | Additional description: Platelet count decreased | | |
| subjects affected / exposed | 14 / 228 (6.14%) | 8 / 216 (3.70%) | 8 / 237 (3.38%) |
| occurrences (all) | 19 | 9 | 8 |
| Procalcitonin increased | Additional description: Procalcitonin increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Reticulocyte count decreased | Additional description: Reticulocyte count decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| SARS-CoV-2 test positive | Additional description: SARS-CoV-2 test positive | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 2 | 1 |
| Serum ferritin decreased | Additional description: Serum ferritin decreased | | |

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|--|--|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Transaminases increased | Additional description: Transaminases increased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Transferrin decreased | Additional description: Transferrin decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin B12 decreased | Additional description: Vitamin B12 decreased | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Weight decreased | Additional description: Weight decreased | | |
| subjects affected / exposed | 7 / 228 (3.07%) | 6 / 216 (2.78%) | 2 / 237 (0.84%) |
| occurrences (all) | 9 | 6 | 2 |
| Weight increased | Additional description: Weight increased | | |
| subjects affected / exposed | 8 / 228 (3.51%) | 5 / 216 (2.31%) | 6 / 237 (2.53%) |
| occurrences (all) | 8 | 9 | 6 |
| White blood cell count decreased | Additional description: White blood cell count decreased | | |
| subjects affected / exposed | 8 / 228 (3.51%) | 9 / 216 (4.17%) | 5 / 237 (2.11%) |
| occurrences (all) | 13 | 9 | 8 |
| White blood cell count increased | Additional description: White blood cell count increased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 1 | 1 |
| Injury, poisoning and procedural complications | | | |
| Arthropod bite | Additional description: Arthropod bite | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 4 / 237 (1.69%) |
| occurrences (all) | 1 | 1 | 4 |
| Animal bite | Additional description: Animal bite | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone contusion | Additional description: Bone contusion | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest injury | Additional description: Chest injury | | |

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|-----------------------------|---|-------------------|-------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Clavicle fracture | Additional description: Clavicle fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | Additional description: Contusion | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 1 | 1 |
| Ear canal injury | Additional description: Ear canal injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epicondylitis | Additional description: Epicondylitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Face injury | Additional description: Face injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | Additional description: Fall | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 3 / 216 (1.39%) | 0 / 237 (0.00%) |
| occurrences (all) | 5 | 4 | 0 |
| Foreign body in eye | Additional description: Foreign body in eye | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fracture | Additional description: Fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Hand fracture | Additional description: Hand fracture | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Head injury | Additional description: Head injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | Additional description: Infusion related reaction | | |
| subjects affected / exposed | 101 / 228 (44.30%) | 65 / 216 (30.09%) | 67 / 237 (28.27%) |
| occurrences (all) | 111 | 74 | 88 |
| Injury | Additional description: Injury | | |

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|--------------------------------|--|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ligament injury | Additional description: Ligament injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Joint capsule rupture | Additional description: Joint capsule rupture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Ligament sprain | Additional description: Ligament sprain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Limb injury | Additional description: Limb injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Mallet finger | Additional description: Mallet finger | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 1 | 1 |
| Meniscus injury | Additional description: Meniscus injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth injury | Additional description: Mouth injury | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Multiple fractures | Additional description: Multiple fractures | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle strain | Additional description: Muscle strain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal injury | Additional description: Nasal injury | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paravenous drug administration | Additional description: Paravenous drug administration | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Procedural pain | Additional description: Procedural pain | | |

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|------------------------------|--|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Post-traumatic neck syndrome | Additional description: Post-traumatic neck syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Road traffic accident | Additional description: Road traffic accident | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Scar | Additional description: Scar | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin abrasion | Additional description: Skin abrasion | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Skin wound | Additional description: Skin wound | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Spinal compression fracture | Additional description: Spinal compression fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spinal fracture | Additional description: Spinal fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Tendon rupture | Additional description: Tendon rupture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Thermal burn | Additional description: Thermal burn | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 1 | 1 |
| Thoracic vertebral fracture | Additional description: Thoracic vertebral fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth injury | Additional description: Tooth injury | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Transfusion reaction | Additional description: Transfusion reaction | | |

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| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Traumatic ear amputation | Additional description: Traumatic ear amputation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Traumatic haematoma | Additional description: Traumatic haematoma | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access complication | Additional description: Vascular access complication | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wrist fracture | Additional description: Wrist fracture | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | Additional description: Wound | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Wound complication | Additional description: Wound complication | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Congenital, familial and genetic disorders | | | |
| Cryptorchism | Additional description: Cryptorchism | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Glycogen storage disease type I | Additional description: Glycogen storage disease type I | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hydrocele | Additional description: Hydrocele | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Ichthyosis | Additional description: Ichthyosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Phimosis | Additional description: Phimosis | | |

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| subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Cardiac disorders | Additional description: Cardiac disorders | | |
| Acute coronary syndrome subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Angina pectoris subjects affected / exposed occurrences (all) | 3 / 228 (1.32%) 3 | 2 / 216 (0.93%) 2 | 4 / 237 (1.69%) 5 |
| Arteriosclerosis coronary artery subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Arrhythmia subjects affected / exposed occurrences (all) | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Atrial fibrillation subjects affected / exposed occurrences (all) | 5 / 228 (2.19%) 5 | 5 / 216 (2.31%) 5 | 5 / 237 (2.11%) 6 |
| Atrial flutter subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 2 / 216 (0.93%) 3 | 1 / 237 (0.42%) 1 |
| Atrial thrombosis subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Atrioventricular block second degree subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Bradycardia subjects affected / exposed occurrences (all) | 1 / 228 (0.44%) 1 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Bundle branch block right subjects affected / exposed occurrences (all) | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Cardiac discomfort subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |

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| Cardiac failure subjects affected / exposed occurrences (all) | Additional description: Cardiac failure | | |
| | 1 / 228 (0.44%) 1 | 3 / 216 (1.39%) 3 | 2 / 237 (0.84%) 2 |
| Cardiovascular disorder subjects affected / exposed occurrences (all) | Additional description: Cardiovascular disorder | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Coronary artery disease subjects affected / exposed occurrences (all) | Additional description: Coronary artery disease | | |
| | 2 / 228 (0.88%) 2 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Coronary artery stenosis subjects affected / exposed occurrences (all) | Additional description: Coronary artery stenosis | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Extrasystoles subjects affected / exposed occurrences (all) | Additional description: Extrasystoles | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Hypertensive heart disease subjects affected / exposed occurrences (all) | Additional description: Hypertensive heart disease | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Myocardial ischaemia subjects affected / exposed occurrences (all) | Additional description: Myocardial ischaemia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Palpitations subjects affected / exposed occurrences (all) | Additional description: Palpitations | | |
| | 3 / 228 (1.32%) 3 | 2 / 216 (0.93%) 2 | 3 / 237 (1.27%) 3 |
| Pericardial effusion subjects affected / exposed occurrences (all) | Additional description: Pericardial effusion | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Right ventricular failure subjects affected / exposed occurrences (all) | Additional description: Right ventricular failure | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Sinus tachycardia subjects affected / exposed occurrences (all) | Additional description: Sinus tachycardia | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Supraventricular tachycardia subjects affected / exposed occurrences (all) | Additional description: Supraventricular tachycardia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Tachycardia subjects affected / exposed occurrences (all) | Additional description: Tachycardia | | |
| | 3 / 228 (1.32%) | 2 / 216 (0.93%) | 4 / 237 (1.69%) |
| | 4 | 2 | 4 |
| Tachycardia paroxysmal subjects affected / exposed occurrences (all) | Additional description: Tachycardia paroxysmal | | |
| | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| | 0 | 1 | 0 |
| Ventricular extrasystoles subjects affected / exposed occurrences (all) | Additional description: Ventricular extrasystoles | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| | 0 | 0 | 2 |
| Nervous system disorders | | | |
| Ageusia subjects affected / exposed occurrences (all) | Additional description: Ageusia | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| Amnesia subjects affected / exposed occurrences (all) | Additional description: Amnesia | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 1 | 0 | 1 |
| Aphasia subjects affected / exposed occurrences (all) | Additional description: Aphasia | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| | 1 | 0 | 2 |
| Ataxia subjects affected / exposed occurrences (all) | Additional description: Ataxia | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| Balance disorder subjects affected / exposed occurrences (all) | Additional description: Balance disorder | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| Burning sensation subjects affected / exposed occurrences (all) | Additional description: Burning sensation | | |
| | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 2 | 0 | 0 |
| Carpal tunnel syndrome subjects affected / exposed occurrences (all) | Additional description: Carpal tunnel syndrome | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 4 / 237 (1.69%) |
| | 1 | 0 | 4 |
| Cervicobrachial syndrome subjects affected / exposed occurrences (all) | Additional description: Cervicobrachial syndrome | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| Carotid artery stenosis | Additional description: Carotid artery stenosis | | |
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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Concentration impairment | Additional description: Concentration impairment | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Cognitive disorder | Additional description: Cognitive disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Cubital tunnel syndrome | Additional description: Cubital tunnel syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed level of consciousness | Additional description: Depressed level of consciousness | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disturbance in attention | Additional description: Disturbance in attention | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 2 / 216 (0.93%) | 3 / 237 (1.27%) |
| occurrences (all) | 5 | 2 | 3 |
| Dizziness | Additional description: Dizziness | | |
| subjects affected / exposed | 21 / 228 (9.21%) | 12 / 216 (5.56%) | 20 / 237 (8.44%) |
| occurrences (all) | 28 | 15 | 24 |
| Dizziness postural | Additional description: Dizziness postural | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysaesthesia | Additional description: Dysaesthesia | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 2 | 2 |
| Dysgeusia | Additional description: Dysgeusia | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 9 / 216 (4.17%) | 3 / 237 (1.27%) |
| occurrences (all) | 6 | 9 | 3 |
| Facial paralysis | Additional description: Facial paralysis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Formication | Additional description: Formication | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hand-arm vibration syndrome | Additional description: Hand-arm vibration syndrome | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Head discomfort | Additional description: Head discomfort | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Headache | Additional description: Headache | | |
| subjects affected / exposed | 36 / 228 (15.79%) | 22 / 216 (10.19%) | 23 / 237 (9.70%) |
| occurrences (all) | 45 | 29 | 26 |
| Hypoaesthesia | Additional description: Hypoaesthesia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 1 | 2 |
| Hypertonia | Additional description: Hypertonia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotonia | Additional description: Hypotonia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Intention tremor | Additional description: Intention tremor | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lumbar radiculopathy | Additional description: Lumbar radiculopathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Memory impairment | Additional description: Memory impairment | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 2 |
| Mental impairment | Additional description: Mental impairment | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Migraine | Additional description: Migraine | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 1 | 1 |
| Muscle spasticity | Additional description: Muscle spasticity | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neuromuscular blockade | Additional description: Neuromuscular blockade | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Olfactory nerve disorder | Additional description: Olfactory nerve disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neuropathy peripheral | Additional description: Neuropathy peripheral | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 4 / 216 (1.85%) | 1 / 237 (0.42%) |
| occurrences (all) | 3 | 4 | 1 |
| Orthostatic intolerance | Additional description: Orthostatic intolerance | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paraesthesia | Additional description: Paraesthesia | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 4 / 216 (1.85%) | 3 / 237 (1.27%) |
| occurrences (all) | 3 | 4 | 3 |
| Parkinson's disease | Additional description: Parkinson's disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Parosmia | Additional description: Parosmia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Peripheral motor neuropathy | Additional description: Peripheral motor neuropathy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | Additional description: Peripheral sensory neuropathy | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 2 / 216 (0.93%) | 5 / 237 (2.11%) |
| occurrences (all) | 4 | 2 | 5 |
| Polyneuropathy | Additional description: Polyneuropathy | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 3 / 216 (1.39%) | 2 / 237 (0.84%) |
| occurrences (all) | 3 | 4 | 2 |
| Post herpetic neuralgia | Additional description: Post herpetic neuralgia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Presyncope | Additional description: Presyncope | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Restless legs syndrome | Additional description: Restless legs syndrome | | |

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|--------------------------------------|--|-------------------|------------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 0 | 2 |
| Sciatica | Additional description: Sciatica | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Sensory disturbance | Additional description: Sensory disturbance | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Syncope | Additional description: Syncope | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 4 / 216 (1.85%) | 2 / 237 (0.84%) |
| occurrences (all) | 4 | 4 | 2 |
| Somnolence | Additional description: Somnolence | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | Additional description: Taste disorder | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 1 | 1 |
| Transient global amnesia | Additional description: Transient global amnesia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tremor | Additional description: Tremor | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 3 | 0 | 1 |
| Trigeminal neuralgia | Additional description: Trigeminal neuralgia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Visual field defect | Additional description: Visual field defect | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 3 |
| Blood and lymphatic system disorders | | | |
| Agranulocytosis | Additional description: Agranulocytosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Anaemia | Additional description: Anaemia | | |
| subjects affected / exposed | 17 / 228 (7.46%) | 31 / 216 (14.35%) | 20 / 237 (8.44%) |
| occurrences (all) | 21 | 42 | 27 |

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|---|---|-------------------------|------------------------|
| Autoimmune haemolytic anaemia subjects affected / exposed occurrences (all) | Additional description: Autoimmune haemolytic anaemia | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Bicytopenia subjects affected / exposed occurrences (all) | Additional description: Bicytopenia | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Eosinophilia subjects affected / exposed occurrences (all) | Additional description: Eosinophilia | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Febrile neutropenia subjects affected / exposed occurrences (all) | Additional description: Febrile neutropenia | | |
| | 2 / 228 (0.88%) 4 | 6 / 216 (2.78%) 6 | 3 / 237 (1.27%) 3 |
| Granulocytopenia subjects affected / exposed occurrences (all) | Additional description: Granulocytopenia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 2 / 237 (0.84%) 2 |
| Haemolysis subjects affected / exposed occurrences (all) | Additional description: Haemolysis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Haemorrhagic diathesis subjects affected / exposed occurrences (all) | Additional description: Haemorrhagic diathesis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Hypoglobulinaemia subjects affected / exposed occurrences (all) | Additional description: Hypoglobulinaemia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Immune thrombocytopenia subjects affected / exposed occurrences (all) | Additional description: Immune thrombocytopenia | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Iron deficiency anaemia subjects affected / exposed occurrences (all) | Additional description: Iron deficiency anaemia | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Leukocytosis subjects affected / exposed occurrences (all) | Additional description: Leukocytosis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 2 / 237 (0.84%) 2 |
| Leukopenia subjects affected / exposed occurrences (all) | Additional description: Leukopenia | | |
| | 20 / 228 (8.77%) 30 | 33 / 216 (15.28%) 48 | 12 / 237 (5.06%) 22 |

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| Lymph node pain subjects affected / exposed occurrences (all) | Additional description: Lymph node pain | | |
| | 2 / 228 (0.88%) 2 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Lymphadenitis subjects affected / exposed occurrences (all) | Additional description: Lymphadenitis | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Lymphadenopathy subjects affected / exposed occurrences (all) | Additional description: Lymphadenopathy | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Macrocytosis subjects affected / exposed occurrences (all) | Additional description: Macrocytosis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Microcytic anaemia subjects affected / exposed occurrences (all) | Additional description: Microcytic anaemia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Neutropenia subjects affected / exposed occurrences (all) | Additional description: Neutropenia | | |
| | 111 / 228 (48.68%) 272 | 107 / 216 (49.54%) 209 | 108 / 237 (45.57%) 231 |
| Pancytopenia subjects affected / exposed occurrences (all) | Additional description: Pancytopenia | | |
| | 0 / 228 (0.00%) 0 | 2 / 216 (0.93%) 2 | 0 / 237 (0.00%) 0 |
| Reticulocytosis subjects affected / exposed occurrences (all) | Additional description: Reticulocytosis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Thrombocytopenia subjects affected / exposed occurrences (all) | Additional description: Thrombocytopenia | | |
| | 34 / 228 (14.91%) 40 | 32 / 216 (14.81%) 44 | 18 / 237 (7.59%) 28 |
| Ear and labyrinth disorders Auditory disorder subjects affected / exposed occurrences (all) | Additional description: Auditory disorder | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Deafness subjects affected / exposed occurrences (all) | Additional description: Deafness | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Deafness unilateral | Additional description: Deafness unilateral | | |

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|-----------------------------|--|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ear haemorrhage | Additional description: Ear haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | Additional description: Ear pain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 3 / 216 (1.39%) | 3 / 237 (1.27%) |
| occurrences (all) | 1 | 3 | 3 |
| Hypoacusis | Additional description: Hypoacusis | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Middle ear effusion | Additional description: Middle ear effusion | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Middle ear inflammation | Additional description: Middle ear inflammation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinnitus | Additional description: Tinnitus | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 0 / 216 (0.00%) | 4 / 237 (1.69%) |
| occurrences (all) | 6 | 0 | 4 |
| Vertigo positional | Additional description: Vertigo positional | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vertigo | Additional description: Vertigo | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 8 / 216 (3.70%) | 9 / 237 (3.80%) |
| occurrences (all) | 6 | 8 | 9 |
| Eye disorders | | | |
| Blepharitis | Additional description: Blepharitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cataract | Additional description: Cataract | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 2 | 0 | 1 |
| Conjunctival haemorrhage | Additional description: Conjunctival haemorrhage | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

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|--|--|----------------------|----------------------|
| Corneal erosion subjects affected / exposed occurrences (all) | Additional description: Corneal erosion | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Diplopia subjects affected / exposed occurrences (all) | Additional description: Diplopia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Dry eye subjects affected / exposed occurrences (all) | Additional description: Dry eye | | |
| | 1 / 228 (0.44%) 1 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Erythema of eyelid subjects affected / exposed occurrences (all) | Additional description: Erythema of eyelid | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Exophthalmos subjects affected / exposed occurrences (all) | Additional description: Exophthalmos | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Eye haemorrhage subjects affected / exposed occurrences (all) | Additional description: Eye haemorrhage | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 2 / 237 (0.84%) 2 |
| Eye inflammation subjects affected / exposed occurrences (all) | Additional description: Eye inflammation | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Eye irritation subjects affected / exposed occurrences (all) | Additional description: Eye irritation | | |
| | 0 / 228 (0.00%) 0 | 2 / 216 (0.93%) 2 | 0 / 237 (0.00%) 0 |
| Eye oedema subjects affected / exposed occurrences (all) | Additional description: Eye oedema | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Eye pain subjects affected / exposed occurrences (all) | Additional description: Eye pain | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Eyelid haematoma subjects affected / exposed occurrences (all) | Additional description: Eyelid haematoma | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Eyelid oedema subjects affected / exposed occurrences (all) | Additional description: Eyelid oedema | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |

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| Eyelid ptosis subjects affected / exposed occurrences (all) | Additional description: Eyelid ptosis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Eye disorder subjects affected / exposed occurrences (all) | Additional description: Eye disorder | | |
| | 2 / 228 (0.88%) 2 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Glaucoma subjects affected / exposed occurrences (all) | Additional description: Glaucoma | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Hyalosis asteroid subjects affected / exposed occurrences (all) | Additional description: Hyalosis asteroid | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Lacrimation increased subjects affected / exposed occurrences (all) | Additional description: Lacrimation increased | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Ocular hyperaemia subjects affected / exposed occurrences (all) | Additional description: Ocular hyperaemia | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Ocular hypertension subjects affected / exposed occurrences (all) | Additional description: Ocular hypertension | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Panophthalmitis subjects affected / exposed occurrences (all) | Additional description: Panophthalmitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Periorbital oedema subjects affected / exposed occurrences (all) | Additional description: Periorbital oedema | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Photophobia subjects affected / exposed occurrences (all) | Additional description: Photophobia | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Retinal haemorrhage subjects affected / exposed occurrences (all) | Additional description: Retinal haemorrhage | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Uveitis subjects affected / exposed occurrences (all) | Additional description: Uveitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Vitreous detachment subjects affected / exposed occurrences (all) | Additional description: Vitreous detachment | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Vitreous disorder subjects affected / exposed occurrences (all) | Additional description: Vitreous disorder | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Vitreous haemorrhage subjects affected / exposed occurrences (all) | Additional description: Vitreous haemorrhage | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Visual impairment subjects affected / exposed occurrences (all) | Additional description: Visual impairment | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 3 / 237 (1.27%) 3 |
| Vision blurred subjects affected / exposed occurrences (all) | Additional description: Vision blurred | | |
| | 4 / 228 (1.75%) 4 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Gastrointestinal disorders | | | |
| | Additional description: Abdominal pain upper | | |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 11 / 228 (4.82%) 12 | 8 / 216 (3.70%) 8 | 11 / 237 (4.64%) 12 |
| Abdominal pain lower subjects affected / exposed occurrences (all) | Additional description: Abdominal pain lower | | |
| | 1 / 228 (0.44%) 1 | 3 / 216 (1.39%) 3 | 0 / 237 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | Additional description: Abdominal pain | | |
| | 6 / 228 (2.63%) 6 | 5 / 216 (2.31%) 6 | 14 / 237 (5.91%) 17 |
| Abdominal distension subjects affected / exposed occurrences (all) | Additional description: Abdominal distension | | |
| | 3 / 228 (1.32%) 3 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Abdominal discomfort subjects affected / exposed occurrences (all) | Additional description: Abdominal discomfort | | |
| | 3 / 228 (1.32%) 3 | 2 / 216 (0.93%) 2 | 4 / 237 (1.69%) 4 |
| Anal ulcer subjects affected / exposed occurrences (all) | Additional description: Anal ulcer | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Anal pruritus | Additional description: Anal pruritus | | |
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| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Anal incontinence | Additional description: Anal incontinence | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Anal haemorrhage | Additional description: Anal haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Anal fissure | Additional description: Anal fissure | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 3 / 216 (1.39%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Angular cheilitis | Additional description: Angular cheilitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aphthous ulcer | Additional description: Aphthous ulcer | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 3 | 0 | 2 |
| Cheilitis | Additional description: Cheilitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Coeliac disease | Additional description: Coeliac disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Colitis | Additional description: Colitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Constipation | Additional description: Constipation | | |
| subjects affected / exposed | 28 / 228 (12.28%) | 64 / 216 (29.63%) | 28 / 237 (11.81%) |
| occurrences (all) | 31 | 73 | 31 |
| Crohn's disease | Additional description: Crohn's disease | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dental caries | Additional description: Dental caries | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Diarrhoea | Additional description: Diarrhoea | | |

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| subjects affected / exposed | 74 / 228 (32.46%) | 27 / 216 (12.50%) | 72 / 237 (30.38%) |
| occurrences (all) | 108 | 31 | 97 |
| Diarrhoea haemorrhagic | Additional description: Diarrhoea haemorrhagic | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Defaecation disorder | Additional description: Defaecation disorder | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diverticulum intestinal | Additional description: Diverticulum intestinal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry mouth | Additional description: Dry mouth | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 5 / 216 (2.31%) | 2 / 237 (0.84%) |
| occurrences (all) | 3 | 5 | 2 |
| Dyspepsia | Additional description: Dyspepsia | | |
| subjects affected / exposed | 17 / 228 (7.46%) | 3 / 216 (1.39%) | 10 / 237 (4.22%) |
| occurrences (all) | 19 | 3 | 10 |
| Dysphagia | Additional description: Dysphagia | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 3 / 216 (1.39%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 3 | 2 |
| Enterovirus infection | Additional description: Enterovirus infection | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epigastric discomfort | Additional description: Epigastric discomfort | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 3 / 237 (1.27%) |
| occurrences (all) | 0 | 0 | 3 |
| Faeces discoloured | Additional description: Faeces discoloured | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastric haemorrhage | Additional description: Gastric haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | Additional description: Flatulence | | |
| subjects affected / exposed | 9 / 228 (3.95%) | 3 / 216 (1.39%) | 4 / 237 (1.69%) |
| occurrences (all) | 11 | 3 | 4 |
| Food poisoning | Additional description: Food poisoning | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Frequent bowel movements | Additional description: Frequent bowel movements | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Giant cell epulis | Additional description: Giant cell epulis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | Additional description: Gingival bleeding | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Gastritis | Additional description: Gastritis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 1 | 1 |
| Gastrointestinal haemorrhage | Additional description: Gastrointestinal haemorrhage | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal motility disorder | Additional description: Gastrointestinal motility disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal pain | Additional description: Gastrointestinal pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal tract irritation | Additional description: Gastrointestinal tract irritation | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrooesophageal reflux disease | Additional description: Gastrooesophageal reflux disease | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 5 / 216 (2.31%) | 9 / 237 (3.80%) |
| occurrences (all) | 2 | 5 | 9 |
| Gingival discolouration | Additional description: Gingival discolouration | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoidal haemorrhage | Additional description: Haemorrhoidal haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haematochezia | Additional description: Haematochezia | | |

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| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 2 | 0 | 1 |
| Haemorrhoids | Additional description: Haemorrhoids | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 1 / 216 (0.46%) | 3 / 237 (1.27%) |
| occurrences (all) | 4 | 1 | 3 |
| Inguinal hernia | Additional description: Inguinal hernia | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 0 | 2 |
| Lip dry | Additional description: Lip dry | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip pain | Additional description: Lip pain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mouth haemorrhage | Additional description: Mouth haemorrhage | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Mouth ulceration | Additional description: Mouth ulceration | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 2 / 216 (0.93%) | 3 / 237 (1.27%) |
| occurrences (all) | 2 | 2 | 6 |
| Nausea | Additional description: Nausea | | |
| subjects affected / exposed | 69 / 228 (30.26%) | 93 / 216 (43.06%) | 64 / 237 (27.00%) |
| occurrences (all) | 87 | 132 | 86 |
| Odynophagia | Additional description: Odynophagia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Oesophagitis | Additional description: Oesophagitis | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 0 | 2 |
| Oral dysaesthesia | Additional description: Oral dysaesthesia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral mucosal blistering | Additional description: Oral mucosal blistering | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral mucosal erythema | Additional description: Oral mucosal erythema | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral pain | Additional description: Oral pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | Additional description: Paraesthesia oral | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Periodontal disease | Additional description: Periodontal disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Proctalgia | Additional description: Proctalgia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rectal haemorrhage | Additional description: Rectal haemorrhage | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Rectal polyp | Additional description: Rectal polyp | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Salivary gland calculus | Additional description: Salivary gland calculus | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stomatitis | Additional description: Stomatitis | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 3 / 216 (1.39%) | 3 / 237 (1.27%) |
| occurrences (all) | 6 | 3 | 5 |
| Tongue coated | Additional description: Tongue coated | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tongue discomfort | Additional description: Tongue discomfort | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Tongue disorder | Additional description: Tongue disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tongue dry | Additional description: Tongue dry | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth loss | Additional description: Tooth loss | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Toothache | Additional description: Toothache | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 4 / 237 (1.69%) |
| occurrences (all) | 1 | 0 | 4 |
| Vomiting | Additional description: Vomiting | | |
| subjects affected / exposed | 14 / 228 (6.14%) | 40 / 216 (18.52%) | 16 / 237 (6.75%) |
| occurrences (all) | 17 | 55 | 21 |
| Hepatobiliary disorders | | | |
| Cholecystitis | Additional description: Cholecystitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholelithiasis | Additional description: Cholelithiasis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatic pain | Additional description: Hepatic pain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Hepatic steatosis | Additional description: Hepatic steatosis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatotoxicity | Additional description: Hepatotoxicity | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Hyperbilirubinaemia | Additional description: Hyperbilirubinaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Liver disorder | Additional description: Liver disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Portal vein dilatation | Additional description: Portal vein dilatation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |

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|--|--|-----------------|-----------------|
| Portal vein thrombosis subjects affected / exposed occurrences (all) | Additional description: Portal vein thrombosis | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| | Additional description: Actinic keratosis | | |
| | 5 / 228 (2.19%) | 0 / 216 (0.00%) | 5 / 237 (2.11%) |
| Actinic keratosis subjects affected / exposed occurrences (all) | 5 | 0 | 5 |
| Alopecia subjects affected / exposed occurrences (all) | Additional description: Alopecia | | |
| | 2 / 228 (0.88%) | 4 / 216 (1.85%) | 6 / 237 (2.53%) |
| | 2 | 4 | 6 |
| Blister subjects affected / exposed occurrences (all) | Additional description: Blister | | |
| | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| | 1 | 1 | 1 |
| Blood blister subjects affected / exposed occurrences (all) | Additional description: Blood blister | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| Cafe au lait spots subjects affected / exposed occurrences (all) | Additional description: Cafe au lait spots | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 0 | 0 | 1 |
| Dermatitis subjects affected / exposed occurrences (all) | Additional description: Dermatitis | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| | 1 | 0 | 2 |
| Dermatitis acneiform subjects affected / exposed occurrences (all) | Additional description: Dermatitis acneiform | | |
| | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| | 1 | 2 | 0 |
| Dermatitis allergic subjects affected / exposed occurrences (all) | Additional description: Dermatitis allergic | | |
| | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| | 1 | 3 | 0 |
| Dermatitis atopic subjects affected / exposed occurrences (all) | Additional description: Dermatitis atopic | | |
| | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 2 | 0 | 0 |
| Dermatitis contact subjects affected / exposed occurrences (all) | Additional description: Dermatitis contact | | |
| | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| | 0 | 1 | 0 |
| Dermatitis exfoliative | Additional description: Dermatitis exfoliative | | |
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|------------------------------------|--|-----------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis exfoliative generalised | Additional description: Dermatitis exfoliative generalised | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Decubitus ulcer | Additional description: Decubitus ulcer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Drug eruption | Additional description: Drug eruption | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | Additional description: Dry skin | | |
| subjects affected / exposed | 16 / 228 (7.02%) | 8 / 216 (3.70%) | 8 / 237 (3.38%) |
| occurrences (all) | 18 | 8 | 8 |
| Ecchymosis | Additional description: Ecchymosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema | Additional description: Eczema | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 3 / 216 (1.39%) | 13 / 237 (5.49%) |
| occurrences (all) | 5 | 3 | 13 |
| Eczema nummular | Additional description: Eczema nummular | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema | Additional description: Erythema | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 3 / 216 (1.39%) | 3 / 237 (1.27%) |
| occurrences (all) | 7 | 4 | 4 |
| Erythema nodosum | Additional description: Erythema nodosum | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eosinophilic cellulitis | Additional description: Eosinophilic cellulitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema multiforme | Additional description: Erythema multiforme | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand dermatitis | Additional description: Hand dermatitis | | |

| | | | |
|-----------------------------|---|-----------------|-----------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | Additional description: Hyperkeratosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperhidrosis | Additional description: Hyperhidrosis | | |
| subjects affected / exposed | 7 / 228 (3.07%) | 3 / 216 (1.39%) | 3 / 237 (1.27%) |
| occurrences (all) | 8 | 3 | 3 |
| Hypertrichosis | Additional description: Hypertrichosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intertrigo | Additional description: Intertrigo | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Lentigo | Additional description: Lentigo | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Lichen planus | Additional description: Lichen planus | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neurodermatitis | Additional description: Neurodermatitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nail discolouration | Additional description: Nail discolouration | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nail dystrophy | Additional description: Nail dystrophy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail pitting | Additional description: Nail pitting | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Nail ridging | Additional description: Nail ridging | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail toxicity | Additional description: Nail toxicity | | |

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|-----------------------------|---|------------------|------------------|
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Night sweats | Additional description: Night sweats | | |
| subjects affected / exposed | 7 / 228 (3.07%) | 8 / 216 (3.70%) | 4 / 237 (1.69%) |
| occurrences (all) | 7 | 9 | 4 |
| Onychoclasia | Additional description: Onychoclasia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 1 | 2 |
| Onycholysis | Additional description: Onycholysis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Papule | Additional description: Papule | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pemphigoid | Additional description: Pemphigoid | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | Additional description: Petechiae | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pigmentation disorder | Additional description: Pigmentation disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash generalised | Additional description: Rash generalised | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash erythematous | Additional description: Rash erythematous | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | Additional description: Pruritus | | |
| subjects affected / exposed | 15 / 228 (6.58%) | 17 / 216 (7.87%) | 19 / 237 (8.02%) |
| occurrences (all) | 16 | 17 | 20 |
| Pruritus generalised | Additional description: Pruritus generalised | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psoriasis | Additional description: Psoriasis | | |

| | | | |
|-----------------------------|--|-------------------|-------------------|
| subjects affected / exposed | 4 / 228 (1.75%) | 2 / 216 (0.93%) | 3 / 237 (1.27%) |
| occurrences (all) | 4 | 2 | 3 |
| Purpura | Additional description: Purpura | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | Additional description: Rash | | |
| subjects affected / exposed | 27 / 228 (11.84%) | 33 / 216 (15.28%) | 32 / 237 (13.50%) |
| occurrences (all) | 29 | 38 | 36 |
| Rash macular | Additional description: Rash macular | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash maculo-papular | Additional description: Rash maculo-papular | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 10 / 216 (4.63%) | 8 / 237 (3.38%) |
| occurrences (all) | 3 | 14 | 9 |
| Rash pruritic | Additional description: Rash pruritic | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Rash papular | Additional description: Rash papular | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rosacea | Additional description: Rosacea | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Solar dermatitis | Additional description: Solar dermatitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin burning sensation | Additional description: Skin burning sensation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin discolouration | Additional description: Skin discolouration | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin discomfort | Additional description: Skin discomfort | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin disorder | Additional description: Skin disorder | | |

| | | | |
|-----------------------------|---|-----------------|-----------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin fissures | Additional description: Skin fissures | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin hypopigmentation | Additional description: Skin hypopigmentation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin irritation | Additional description: Skin irritation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin lesion | Additional description: Skin lesion | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Skin mass | Additional description: Skin mass | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Skin ulcer | Additional description: Skin ulcer | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Suggillation | Additional description: Suggillation | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Telangiectasia | Additional description: Telangiectasia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Toxic skin eruption | Additional description: Toxic skin eruption | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Urticaria | Additional description: Urticaria | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 3 / 216 (1.39%) | 2 / 237 (0.84%) |
| occurrences (all) | 1 | 3 | 3 |
| Renal and urinary disorders | | | |
| Acute kidney injury | Additional description: Acute kidney injury | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 1 | 2 |

| | | | |
|------------------------------|--|-----------------|-----------------|
| Chromaturia | Additional description: Chromaturia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Chronic kidney disease | Additional description: Chronic kidney disease | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cystitis noninfective | Additional description: Cystitis noninfective | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysuria | Additional description: Dysuria | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 6 / 216 (2.78%) | 1 / 237 (0.42%) |
| occurrences (all) | 4 | 6 | 1 |
| Haematuria | Additional description: Haematuria | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| occurrences (all) | 1 | 2 | 2 |
| Hydronephrosis | Additional description: Hydronephrosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Incontinence | Additional description: Incontinence | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Kidney congestion | Additional description: Kidney congestion | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Leukocyturia | Additional description: Leukocyturia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower urinary tract symptoms | Additional description: Lower urinary tract symptoms | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Micturition disorder | Additional description: Micturition disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Micturition urgency | Additional description: Micturition urgency | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|--|----------------------|----------------------|
| Nocturia subjects affected / exposed occurrences (all) | Additional description: Nocturia | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 4 / 237 (1.69%) 4 |
| Pollakiuria subjects affected / exposed occurrences (all) | Additional description: Pollakiuria | | |
| | 3 / 228 (1.32%) 3 | 2 / 216 (0.93%) 2 | 2 / 237 (0.84%) 2 |
| Polyuria subjects affected / exposed occurrences (all) | Additional description: Polyuria | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Renal colic subjects affected / exposed occurrences (all) | Additional description: Renal colic | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Renal cyst subjects affected / exposed occurrences (all) | Additional description: Renal cyst | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Renal failure subjects affected / exposed occurrences (all) | Additional description: Renal failure | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 2 |
| Renal pain subjects affected / exposed occurrences (all) | Additional description: Renal pain | | |
| | 0 / 228 (0.00%) 0 | 3 / 216 (1.39%) 3 | 0 / 237 (0.00%) 0 |
| Strangury subjects affected / exposed occurrences (all) | Additional description: Strangury | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Urinary incontinence subjects affected / exposed occurrences (all) | Additional description: Urinary incontinence | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Urinary tract pain subjects affected / exposed occurrences (all) | Additional description: Urinary tract pain | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Urinary tract obstruction subjects affected / exposed occurrences (all) | Additional description: Urinary tract obstruction | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Urinary tract inflammation subjects affected / exposed occurrences (all) | Additional description: Urinary tract inflammation | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

| | | | |
|---|---|------------------|-------------------|
| Urinary retention subjects affected / exposed occurrences (all) | Additional description: Urinary retention | | |
| | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| | 3 | 1 | 2 |
| Urge incontinence subjects affected / exposed occurrences (all) | Additional description: Urge incontinence | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| Endocrine disorders Goitre subjects affected / exposed occurrences (all) Hyperthyroidism subjects affected / exposed occurrences (all) Hypothyroidism subjects affected / exposed occurrences (all) Thyroid cyst subjects affected / exposed occurrences (all) | | | |
| | Additional description: Goitre | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 0 | 0 | 0 |
| | Additional description: Hyperthyroidism | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 1 | 0 | 0 |
| | Additional description: Hypothyroidism | | |
| | 3 / 228 (1.32%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| | 3 | 0 | 2 |
| | Additional description: Thyroid cyst | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders Arthropathy subjects affected / exposed occurrences (all) Arthritis subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Bone pain subjects affected / exposed occurrences (all) Bursal haematoma | | | |
| | Additional description: Arthropathy | | |
| | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| | 2 | 0 | 1 |
| | Additional description: Arthritis | | |
| | 3 / 228 (1.32%) | 2 / 216 (0.93%) | 4 / 237 (1.69%) |
| | 4 | 3 | 5 |
| | Additional description: Arthralgia | | |
| | 33 / 228 (14.47%) | 8 / 216 (3.70%) | 25 / 237 (10.55%) |
| | 42 | 8 | 26 |
| | Additional description: Back pain | | |
| | 24 / 228 (10.53%) | 12 / 216 (5.56%) | 26 / 237 (10.97%) |
| | 26 | 13 | 27 |
| | Additional description: Bone pain | | |
| | 10 / 228 (4.39%) | 2 / 216 (0.93%) | 6 / 237 (2.53%) |
| | 10 | 2 | 6 |
| | Additional description: Bursal haematoma | | |

| | | | |
|---------------------------------|---|-----------------|-----------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bursitis | Additional description: Bursitis | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Cervical spinal stenosis | Additional description: Cervical spinal stenosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Exostosis | Additional description: Exostosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Fibromyalgia | Additional description: Fibromyalgia | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 2 | 0 | 1 |
| Flank pain | Additional description: Flank pain | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 3 / 216 (1.39%) | 1 / 237 (0.42%) |
| occurrences (all) | 4 | 3 | 1 |
| Groin pain | Additional description: Groin pain | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Hypercreatinaemia | Additional description: Hypercreatinaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc disorder | Additional description: Intervertebral disc disorder | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intervertebral disc protrusion | Additional description: Intervertebral disc protrusion | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 2 | 0 | 1 |
| Joint effusion | Additional description: Joint effusion | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Joint range of motion decreased | Additional description: Joint range of motion decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 1 | 1 |
| Joint swelling | Additional description: Joint swelling | | |

| | | | |
|-----------------------------|--|-----------------|------------------|
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 3 / 237 (1.27%) |
| occurrences (all) | 1 | 0 | 4 |
| Limb discomfort | Additional description: Limb discomfort | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mobility decreased | Additional description: Mobility decreased | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle fatigue | Additional description: Muscle fatigue | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 2 |
| Muscle hypertrophy | Additional description: Muscle hypertrophy | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle spasms | Additional description: Muscle spasms | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 5 / 216 (2.31%) | 10 / 237 (4.22%) |
| occurrences (all) | 7 | 5 | 11 |
| Muscle tightness | Additional description: Muscle tightness | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle twitching | Additional description: Muscle twitching | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | Additional description: Muscular weakness | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Musculoskeletal chest pain | Additional description: Musculoskeletal chest pain | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Musculoskeletal discomfort | Additional description: Musculoskeletal discomfort | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | Additional description: Musculoskeletal pain | | |
| subjects affected / exposed | 8 / 228 (3.51%) | 3 / 216 (1.39%) | 12 / 237 (5.06%) |
| occurrences (all) | 8 | 3 | 12 |
| Musculoskeletal stiffness | Additional description: Musculoskeletal stiffness | | |

| | | | |
|-----------------------------|--|-----------------|------------------|
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 3 / 237 (1.27%) |
| occurrences (all) | 2 | 1 | 3 |
| Myalgia | Additional description: Myalgia | | |
| subjects affected / exposed | 16 / 228 (7.02%) | 9 / 216 (4.17%) | 18 / 237 (7.59%) |
| occurrences (all) | 17 | 13 | 19 |
| Neck pain | Additional description: Neck pain | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 1 / 216 (0.46%) | 5 / 237 (2.11%) |
| occurrences (all) | 5 | 1 | 5 |
| Myositis | Additional description: Myositis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Osteoarthritis | Additional description: Osteoarthritis | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 0 / 216 (0.00%) | 4 / 237 (1.69%) |
| occurrences (all) | 3 | 0 | 4 |
| Osteonecrosis | Additional description: Osteonecrosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Osteoporosis | Additional description: Osteoporosis | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Pain in extremity | Additional description: Pain in extremity | | |
| subjects affected / exposed | 9 / 228 (3.95%) | 4 / 216 (1.85%) | 12 / 237 (5.06%) |
| occurrences (all) | 9 | 6 | 13 |
| Pain in jaw | Additional description: Pain in jaw | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 2 | 0 | 1 |
| Periarthritis | Additional description: Periarthritis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polyarthritis | Additional description: Polyarthritis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polymyalgia rheumatica | Additional description: Polymyalgia rheumatica | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Psoriatic arthropathy | Additional description: Psoriatic arthropathy | | |

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| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Rheumatic disorder | Additional description: Rheumatic disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spinal column stenosis | Additional description: Spinal column stenosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Spinal pain | Additional description: Spinal pain | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Tendon disorder | Additional description: Tendon disorder | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Tendonitis | Additional description: Tendonitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 0 | 1 |
| Vertebral foraminal stenosis | Additional description: Vertebral foraminal stenosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Infections and infestations | | | |
| Abscess limb | Additional description: Abscess limb | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Abdominal infection | Additional description: Abdominal infection | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Acarodermatitis | Additional description: Acarodermatitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abscess | Additional description: Abscess | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Acute sinusitis | Additional description: Acute sinusitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |

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| Atypical pneumonia subjects affected / exposed occurrences (all) | Additional description: Atypical pneumonia | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Bacterial blepharitis subjects affected / exposed occurrences (all) | Additional description: Bacterial blepharitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Bacterial food poisoning subjects affected / exposed occurrences (all) | Additional description: Bacterial food poisoning | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Bacterial infection subjects affected / exposed occurrences (all) | Additional description: Bacterial infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Asymptomatic COVID-19 subjects affected / exposed occurrences (all) | Additional description: Asymptomatic COVID-19 | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Bacterial prostatitis subjects affected / exposed occurrences (all) | Additional description: Bacterial prostatitis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Bacteriuria subjects affected / exposed occurrences (all) | Additional description: Bacteriuria | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Body tinea subjects affected / exposed occurrences (all) | Additional description: Body tinea | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Borrelia infection subjects affected / exposed occurrences (all) | Additional description: Borrelia infection | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Bronchitis bacterial subjects affected / exposed occurrences (all) | Additional description: Bronchitis bacterial | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Bronchopulmonary aspergillosis subjects affected / exposed occurrences (all) | Additional description: Bronchopulmonary aspergillosis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Bursitis infective subjects affected / exposed occurrences (all) | Additional description: Bursitis infective | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Campylobacter gastroenteritis subjects affected / exposed occurrences (all) | Additional description: Campylobacter gastroenteritis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Candida infection subjects affected / exposed occurrences (all) | Additional description: Candida infection | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Bronchitis subjects affected / exposed occurrences (all) | Additional description: Bronchitis | | |
| | 17 / 228 (7.46%) 22 | 19 / 216 (8.80%) 19 | 23 / 237 (9.70%) 24 |
| Cellulitis subjects affected / exposed occurrences (all) | Additional description: Cellulitis | | |
| | 2 / 228 (0.88%) 2 | 1 / 216 (0.46%) 1 | 3 / 237 (1.27%) 3 |
| Chronic sinusitis subjects affected / exposed occurrences (all) | Additional description: Chronic sinusitis | | |
| | 2 / 228 (0.88%) 2 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Clostridium difficile colitis subjects affected / exposed occurrences (all) | Additional description: Clostridium difficile colitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Clostridium difficile infection subjects affected / exposed occurrences (all) | Additional description: Clostridium difficile infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Conjunctivitis subjects affected / exposed occurrences (all) | Additional description: Conjunctivitis | | |
| | 8 / 228 (3.51%) 10 | 2 / 216 (0.93%) 3 | 1 / 237 (0.42%) 1 |
| COVID-19 subjects affected / exposed occurrences (all) | Additional description: COVID-19 | | |
| | 37 / 228 (16.23%) 42 | 35 / 216 (16.20%) 36 | 36 / 237 (15.19%) 41 |
| COVID-19 pneumonia subjects affected / exposed occurrences (all) | Additional description: COVID-19 pneumonia | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Cystitis subjects affected / exposed occurrences (all) | Additional description: Cystitis | | |
| | 6 / 228 (2.63%) 9 | 7 / 216 (3.24%) 8 | 8 / 237 (3.38%) 11 |
| Cytomegalovirus infection subjects affected / exposed occurrences (all) | Additional description: Cytomegalovirus infection | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Dacryocanaliculitis subjects affected / exposed occurrences (all) | Additional description: Dacryocanaliculitis | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Dacryocystitis subjects affected / exposed occurrences (all) | Additional description: Dacryocystitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Device related infection subjects affected / exposed occurrences (all) | Additional description: Device related infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Dengue fever subjects affected / exposed occurrences (all) | Additional description: Dengue fever | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Diverticulitis subjects affected / exposed occurrences (all) | Additional description: Diverticulitis | | |
| | 2 / 228 (0.88%) 2 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Ear infection subjects affected / exposed occurrences (all) | Additional description: Ear infection | | |
| | 2 / 228 (0.88%) 2 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Ear infection bacterial subjects affected / exposed occurrences (all) | Additional description: Ear infection bacterial | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Erythema migrans subjects affected / exposed occurrences (all) | Additional description: Erythema migrans | | |
| | 0 / 228 (0.00%) 0 | 2 / 216 (0.93%) 2 | 0 / 237 (0.00%) 0 |
| Enterococcal infection subjects affected / exposed occurrences (all) | Additional description: Enterococcal infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Enterococcal sepsis subjects affected / exposed occurrences (all) | Additional description: Enterococcal sepsis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Epididymitis subjects affected / exposed occurrences (all) | Additional description: Epididymitis | | |
| | 2 / 228 (0.88%) 3 | 0 / 216 (0.00%) 0 | 2 / 237 (0.84%) 3 |
| Erysipelas subjects affected / exposed occurrences (all) | Additional description: Erysipelas | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 3 / 237 (1.27%) 3 |

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| Eye infection | Additional description: Eye infection | | |
| | 7 / 228 (3.07%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| subjects affected / exposed | 8 | 0 | 2 |
| occurrences (all) | | | |
| Eyelid infection | Additional description: Eyelid infection | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| subjects affected / exposed | 0 | 0 | 1 |
| occurrences (all) | | | |
| Febrile infection | Additional description: Febrile infection | | |
| | 1 / 228 (0.44%) | 3 / 216 (1.39%) | 1 / 237 (0.42%) |
| subjects affected / exposed | 1 | 3 | 1 |
| occurrences (all) | | | |
| Folliculitis | Additional description: Folliculitis | | |
| | 4 / 228 (1.75%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| subjects affected / exposed | 4 | 2 | 4 |
| occurrences (all) | | | |
| Fungal infection | Additional description: Fungal infection | | |
| | 1 / 228 (0.44%) | 3 / 216 (1.39%) | 2 / 237 (0.84%) |
| subjects affected / exposed | 1 | 3 | 2 |
| occurrences (all) | | | |
| Fungal skin infection | Additional description: Fungal skin infection | | |
| | 2 / 228 (0.88%) | 3 / 216 (1.39%) | 1 / 237 (0.42%) |
| subjects affected / exposed | 2 | 3 | 1 |
| occurrences (all) | | | |
| Furuncle | Additional description: Furuncle | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| subjects affected / exposed | 0 | 0 | 0 |
| occurrences (all) | | | |
| Genital infection fungal | Additional description: Genital infection fungal | | |
| | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| subjects affected / exposed | 0 | 0 | 0 |
| occurrences (all) | | | |
| Genital herpes | Additional description: Genital herpes | | |
| | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| subjects affected / exposed | 0 | 1 | 0 |
| occurrences (all) | | | |
| Giardiasis | Additional description: Giardiasis | | |
| | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| subjects affected / exposed | 1 | 0 | 0 |
| occurrences (all) | | | |
| Gastric infection | Additional description: Gastric infection | | |
| | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| subjects affected / exposed | 0 | 1 | 0 |
| occurrences (all) | | | |
| Gastroenteritis | Additional description: Gastroenteritis | | |
| | 3 / 228 (1.32%) | 6 / 216 (2.78%) | 5 / 237 (2.11%) |
| subjects affected / exposed | 3 | 6 | 5 |
| occurrences (all) | | | |

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| Gastroenteritis caliciviral subjects affected / exposed occurrences (all) | Additional description: Gastroenteritis caliciviral | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Gastroenteritis viral subjects affected / exposed occurrences (all) | Additional description: Gastroenteritis viral | | |
| | 1 / 228 (0.44%) 1 | 3 / 216 (1.39%) 3 | 0 / 237 (0.00%) 0 |
| Gastrointestinal disorders subjects affected / exposed occurrences (all) | Additional description: Gastrointestinal disorders | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Gastrointestinal infection subjects affected / exposed occurrences (all) | Additional description: Gastrointestinal infection | | |
| | 4 / 228 (1.75%) 4 | 2 / 216 (0.93%) 2 | 3 / 237 (1.27%) 3 |
| Haemophilus infection subjects affected / exposed occurrences (all) | Additional description: Haemophilus infection | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Gingivitis subjects affected / exposed occurrences (all) | Additional description: Gingivitis | | |
| | 1 / 228 (0.44%) 1 | 3 / 216 (1.39%) 3 | 2 / 237 (0.84%) 2 |
| Herpes infection subjects affected / exposed occurrences (all) | Additional description: Herpes infection | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Helicobacter gastritis subjects affected / exposed occurrences (all) | Additional description: Helicobacter gastritis | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 3 / 237 (1.27%) 3 |
| Hepatitis B reactivation subjects affected / exposed occurrences (all) | Additional description: Hepatitis B reactivation | | |
| | 2 / 228 (0.88%) 2 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Hepatitis E subjects affected / exposed occurrences (all) | Additional description: Hepatitis E | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Hepatitis viral subjects affected / exposed occurrences (all) | Additional description: Hepatitis viral | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Herpes dermatitis subjects affected / exposed occurrences (all) | Additional description: Herpes dermatitis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Herpes simplex subjects affected / exposed occurrences (all) | Additional description: Herpes simplex | | |
| | 6 / 228 (2.63%) 9 | 0 / 216 (0.00%) 0 | 4 / 237 (1.69%) 5 |
| Herpes simplex reactivation subjects affected / exposed occurrences (all) | Additional description: Herpes simplex reactivation | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Hordeolum subjects affected / exposed occurrences (all) | Additional description: Hordeolum | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Herpes zoster subjects affected / exposed occurrences (all) | Additional description: Herpes zoster | | |
| | 9 / 228 (3.95%) 9 | 21 / 216 (9.72%) 24 | 13 / 237 (5.49%) 13 |
| Herpes virus infection subjects affected / exposed occurrences (all) | Additional description: Herpes virus infection | | |
| | 3 / 228 (1.32%) 5 | 2 / 216 (0.93%) 3 | 3 / 237 (1.27%) 3 |
| Herpes viral infections subjects affected / exposed occurrences (all) | Additional description: Herpes viral infections | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Infection subjects affected / exposed occurrences (all) | Additional description: Infection | | |
| | 14 / 228 (6.14%) 17 | 20 / 216 (9.26%) 26 | 7 / 237 (2.95%) 11 |
| Infection susceptibility increased subjects affected / exposed occurrences (all) | Additional description: Infection susceptibility increased | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Infectious colitis subjects affected / exposed occurrences (all) | Additional description: Infectious colitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Infective iritis subjects affected / exposed occurrences (all) | Additional description: Infective iritis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Impetigo subjects affected / exposed occurrences (all) | Additional description: Impetigo | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Infected bite subjects affected / exposed occurrences (all) | Additional description: Infected bite | | |
| | 2 / 228 (0.88%) 2 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Infected dermal cyst subjects affected / exposed occurrences (all) | Additional description: Infected dermal cyst | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Infected skin ulcer subjects affected / exposed occurrences (all) | Additional description: Infected skin ulcer | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Injection site cellulitis subjects affected / exposed occurrences (all) | Additional description: Injection site cellulitis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Influenza subjects affected / exposed occurrences (all) | Additional description: Influenza | | |
| | 9 / 228 (3.95%) 10 | 9 / 216 (4.17%) 10 | 7 / 237 (2.95%) 8 |
| Joint abscess subjects affected / exposed occurrences (all) | Additional description: Joint abscess | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Kidney infection subjects affected / exposed occurrences (all) | Additional description: Kidney infection | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Labyrinthitis subjects affected / exposed occurrences (all) | Additional description: Labyrinthitis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Laryngitis subjects affected / exposed occurrences (all) | Additional description: Laryngitis | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Lip infection subjects affected / exposed occurrences (all) | Additional description: Lip infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Localised infection subjects affected / exposed occurrences (all) | Additional description: Localised infection | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Lower respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Lower respiratory tract infection | | |
| | 3 / 228 (1.32%) 4 | 4 / 216 (1.85%) 5 | 1 / 237 (0.42%) 1 |
| Lyme disease subjects affected / exposed occurrences (all) | Additional description: Lyme disease | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 3 / 237 (1.27%) 3 |

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| Lymph gland infection subjects affected / exposed occurrences (all) | Additional description: Lymph gland infection | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Metapneumovirus infection subjects affected / exposed occurrences (all) | Additional description: Metapneumovirus infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Mucosal infection subjects affected / exposed occurrences (all) | Additional description: Mucosal infection | | |
| | 3 / 228 (1.32%) 3 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Nail infection subjects affected / exposed occurrences (all) | Additional description: Nail infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Nasal candidiasis subjects affected / exposed occurrences (all) | Additional description: Nasal candidiasis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | Additional description: Nasopharyngitis | | |
| | 70 / 228 (30.70%) 99 | 44 / 216 (20.37%) 61 | 55 / 237 (23.21%) 81 |
| Onychomycosis subjects affected / exposed occurrences (all) | Additional description: Onychomycosis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 2 / 237 (0.84%) 2 |
| Neutropenic infection subjects affected / exposed occurrences (all) | Additional description: Neutropenic infection | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Omphalitis subjects affected / exposed occurrences (all) | Additional description: Omphalitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Ophthalmic herpes zoster subjects affected / exposed occurrences (all) | Additional description: Ophthalmic herpes zoster | | |
| | 0 / 228 (0.00%) 0 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Oral candidiasis subjects affected / exposed occurrences (all) | Additional description: Oral candidiasis | | |
| | 1 / 228 (0.44%) 1 | 6 / 216 (2.78%) 6 | 7 / 237 (2.95%) 8 |
| Oral fungal infection subjects affected / exposed occurrences (all) | Additional description: Oral fungal infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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| Oral herpes subjects affected / exposed occurrences (all) | Additional description: Oral herpes | | |
| | 12 / 228 (5.26%) 12 | 9 / 216 (4.17%) 12 | 14 / 237 (5.91%) 16 |
| Oral infection subjects affected / exposed occurrences (all) | Additional description: Oral infection | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Oropharyngeal candidiasis subjects affected / exposed occurrences (all) | Additional description: Oropharyngeal candidiasis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Osteomyelitis subjects affected / exposed occurrences (all) | Additional description: Osteomyelitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Otitis media subjects affected / exposed occurrences (all) | Additional description: Otitis media | | |
| | 5 / 228 (2.19%) 5 | 3 / 216 (1.39%) 3 | 3 / 237 (1.27%) 3 |
| Otitis media acute subjects affected / exposed occurrences (all) | Additional description: Otitis media acute | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Otitis media chronic subjects affected / exposed occurrences (all) | Additional description: Otitis media chronic | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Penile infection subjects affected / exposed occurrences (all) | Additional description: Penile infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Papilloma viral infection subjects affected / exposed occurrences (all) | Additional description: Papilloma viral infection | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |
| Parainfluenzae virus infection subjects affected / exposed occurrences (all) | Additional description: Parainfluenzae virus infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Paronychia subjects affected / exposed occurrences (all) | Additional description: Paronychia | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Parotitis subjects affected / exposed occurrences (all) | Additional description: Parotitis | | |
| | 0 / 228 (0.00%) 0 | 2 / 216 (0.93%) 2 | 0 / 237 (0.00%) 0 |

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| Peritonsillar abscess | Additional description: Peritonsillar abscess | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | Additional description: Pharyngitis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 2 / 216 (0.93%) | 1 / 237 (0.42%) |
| occurrences (all) | 1 | 2 | 1 |
| Pharyngitis bacterial | Additional description: Pharyngitis bacterial | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngotonsillitis | Additional description: Pharyngotonsillitis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonia mycoplasmal | Additional description: Pneumonia mycoplasmal | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia streptococcal | Additional description: Pneumonia streptococcal | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Post-acute COVID-19 syndrome | Additional description: Post-acute COVID-19 syndrome | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Postoperative wound infection | Additional description: Postoperative wound infection | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumonia | Additional description: Pneumonia | | |
| subjects affected / exposed | 17 / 228 (7.46%) | 17 / 216 (7.87%) | 10 / 237 (4.22%) |
| occurrences (all) | 19 | 21 | 14 |
| Pulpitis dental | Additional description: Pulpitis dental | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyelonephritis | Additional description: Pyelonephritis | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyuria | Additional description: Pyuria | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|------------------------|------------------------|
| Respiratory syncytial virus infection subjects affected / exposed occurrences (all) | Additional description: Respiratory syncytial virus infection | | |
| | 1 / 228 (0.44%) 1 | 2 / 216 (0.93%) 2 | 0 / 237 (0.00%) 0 |
| Respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Respiratory tract infection | | |
| | 16 / 228 (7.02%) 16 | 13 / 216 (6.02%) 15 | 17 / 237 (7.17%) 21 |
| Respiratory tract infection viral subjects affected / exposed occurrences (all) | Additional description: Respiratory tract infection viral | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Rhinitis subjects affected / exposed occurrences (all) | Additional description: Rhinitis | | |
| | 8 / 228 (3.51%) 9 | 5 / 216 (2.31%) 5 | 5 / 237 (2.11%) 5 |
| Sialoadenitis subjects affected / exposed occurrences (all) | Additional description: Sialoadenitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Root canal infection subjects affected / exposed occurrences (all) | Additional description: Root canal infection | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Scarlet fever subjects affected / exposed occurrences (all) | Additional description: Scarlet fever | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Scrotal infection subjects affected / exposed occurrences (all) | Additional description: Scrotal infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Sebaceous gland infection subjects affected / exposed occurrences (all) | Additional description: Sebaceous gland infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Sinusitis subjects affected / exposed occurrences (all) | Additional description: Sinusitis | | |
| | 25 / 228 (10.96%) 38 | 8 / 216 (3.70%) 8 | 12 / 237 (5.06%) 14 |
| Skin infection subjects affected / exposed occurrences (all) | Additional description: Skin infection | | |
| | 5 / 228 (2.19%) 5 | 5 / 216 (2.31%) 5 | 3 / 237 (1.27%) 3 |
| Soft tissue infection subjects affected / exposed occurrences (all) | Additional description: Soft tissue infection | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |

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|--|--|----------------------|----------------------|
| Staphylococcal infection subjects affected / exposed occurrences (all) | Additional description: Staphylococcal infection | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 2 / 237 (0.84%) 2 |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | Additional description: Subcutaneous abscess | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Sycosis barbae subjects affected / exposed occurrences (all) | Additional description: Sycosis barbae | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Tinea pedis subjects affected / exposed occurrences (all) | Additional description: Tinea pedis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Tinea infection subjects affected / exposed occurrences (all) | Additional description: Tinea infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Tonsillitis subjects affected / exposed occurrences (all) | Additional description: Tonsillitis | | |
| | 1 / 228 (0.44%) 1 | 2 / 216 (0.93%) 2 | 1 / 237 (0.42%) 1 |
| Tooth abscess subjects affected / exposed occurrences (all) | Additional description: Tooth abscess | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Tooth infection subjects affected / exposed occurrences (all) | Additional description: Tooth infection | | |
| | 4 / 228 (1.75%) 4 | 1 / 216 (0.46%) 1 | 9 / 237 (3.80%) 9 |
| Tracheitis subjects affected / exposed occurrences (all) | Additional description: Tracheitis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Urethritis subjects affected / exposed occurrences (all) | Additional description: Urethritis | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |
| Vaginal infection subjects affected / exposed occurrences (all) | Additional description: Vaginal infection | | |
| | 0 / 228 (0.00%) 0 | 1 / 216 (0.46%) 1 | 4 / 237 (1.69%) 5 |
| Urosepsis subjects affected / exposed occurrences (all) | Additional description: Urosepsis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |

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|---|---|-------------------------|-------------------------|
| Urinary tract infection viral subjects affected / exposed occurrences (all) | Additional description: Urinary tract infection viral | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Urinary tract infection bacterial subjects affected / exposed occurrences (all) | Additional description: Urinary tract infection bacterial | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Urinary tract infection subjects affected / exposed occurrences (all) | Additional description: Urinary tract infection | | |
| | 24 / 228 (10.53%) 27 | 16 / 216 (7.41%) 20 | 14 / 237 (5.91%) 22 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Upper respiratory tract infection | | |
| | 36 / 228 (15.79%) 52 | 39 / 216 (18.06%) 56 | 24 / 237 (10.13%) 33 |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Viral upper respiratory tract infection | | |
| | 1 / 228 (0.44%) 1 | 1 / 216 (0.46%) 1 | 2 / 237 (0.84%) 3 |
| Viral sinusitis subjects affected / exposed occurrences (all) | Additional description: Viral sinusitis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Viral infection subjects affected / exposed occurrences (all) | Additional description: Viral infection | | |
| | 5 / 228 (2.19%) 7 | 3 / 216 (1.39%) 3 | 5 / 237 (2.11%) 5 |
| Vestibular neuronitis subjects affected / exposed occurrences (all) | Additional description: Vestibular neuronitis | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Varicella zoster virus infection subjects affected / exposed occurrences (all) | Additional description: Varicella zoster virus infection | | |
| | 0 / 228 (0.00%) 0 | 3 / 216 (1.39%) 3 | 0 / 237 (0.00%) 0 |
| Vulvovaginal candidiasis subjects affected / exposed occurrences (all) | Additional description: Vulvovaginal candidiasis | | |
| | 1 / 228 (0.44%) 1 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Vulvovaginal mycotic infection subjects affected / exposed occurrences (all) | Additional description: Vulvovaginal mycotic infection | | |
| | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Wound infection subjects affected / exposed occurrences (all) | Additional description: Wound infection | | |
| | 2 / 228 (0.88%) 2 | 1 / 216 (0.46%) 1 | 1 / 237 (0.42%) 1 |

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|------------------------------------|--|------------------|------------------|
| Metabolism and nutrition disorders | | | |
| Abnormal weight gain | Additional description: Abnormal weight gain | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Acidosis | Additional description: Acidosis | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Alcohol intolerance | Additional description: Alcohol intolerance | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 0 | 0 | 1 |
| Decreased appetite | Additional description: Decreased appetite | | |
| subjects affected / exposed | 11 / 228 (4.82%) | 14 / 216 (6.48%) | 12 / 237 (5.06%) |
| occurrences (all) | 14 | 18 | 12 |
| Diabetes mellitus | Additional description: Diabetes mellitus | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dehydration | Additional description: Dehydration | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dyslipidaemia | Additional description: Dyslipidaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fluid overload | Additional description: Fluid overload | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Folate deficiency | Additional description: Folate deficiency | | |
| subjects affected / exposed | 3 / 228 (1.32%) | 1 / 216 (0.46%) | 1 / 237 (0.42%) |
| occurrences (all) | 3 | 1 | 1 |
| Gout | Additional description: Gout | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 2 / 216 (0.93%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 2 | 2 |
| Hyperphosphataemia | Additional description: Hyperphosphataemia | | |
| subjects affected / exposed | 4 / 228 (1.75%) | 0 / 216 (0.00%) | 10 / 237 (4.22%) |
| occurrences (all) | 4 | 0 | 14 |
| Hyperkalaemia | Additional description: Hyperkalaemia | | |

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|-----------------------------|---|-----------------|------------------|
| subjects affected / exposed | 8 / 228 (3.51%) | 6 / 216 (2.78%) | 18 / 237 (7.59%) |
| occurrences (all) | 11 | 6 | 26 |
| Hyperglycaemia | Additional description: Hyperglycaemia | | |
| subjects affected / exposed | 6 / 228 (2.63%) | 3 / 216 (1.39%) | 1 / 237 (0.42%) |
| occurrences (all) | 6 | 3 | 1 |
| Hypercholesterolaemia | Additional description: Hypercholesterolaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 1 / 216 (0.46%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypercalcaemia | Additional description: Hypercalcaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | Additional description: Hyponatraemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Hypomagnesaemia | Additional description: Hypomagnesaemia | | |
| subjects affected / exposed | 1 / 228 (0.44%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypokalaemia | Additional description: Hypokalaemia | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 4 / 216 (1.85%) | 4 / 237 (1.69%) |
| occurrences (all) | 7 | 4 | 5 |
| Hypoferritinaemia | Additional description: Hypoferritinaemia | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | Additional description: Hypocalcaemia | | |
| subjects affected / exposed | 2 / 228 (0.88%) | 1 / 216 (0.46%) | 2 / 237 (0.84%) |
| occurrences (all) | 2 | 1 | 3 |
| Hyperuricaemia | Additional description: Hyperuricaemia | | |
| subjects affected / exposed | 7 / 228 (3.07%) | 2 / 216 (0.93%) | 9 / 237 (3.80%) |
| occurrences (all) | 8 | 2 | 9 |
| Hypophosphataemia | Additional description: Hypophosphataemia | | |
| subjects affected / exposed | 5 / 228 (2.19%) | 0 / 216 (0.00%) | 1 / 237 (0.42%) |
| occurrences (all) | 11 | 0 | 2 |
| Increased appetite | Additional description: Increased appetite | | |
| subjects affected / exposed | 0 / 228 (0.00%) | 0 / 216 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency | Additional description: Iron deficiency | | |

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|--|--|----------------------|------------------------|
| subjects affected / exposed occurrences (all) | 4 / 228 (1.75%) 4 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Iron overload | Additional description: Iron overload | | |
| subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Obesity | Additional description: Obesity | | |
| subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 0 / 237 (0.00%) 0 |
| Tumour lysis syndrome | Additional description: Tumour lysis syndrome | | |
| subjects affected / exposed occurrences (all) | 17 / 228 (7.46%) 20 | 7 / 216 (3.24%) 7 | 19 / 237 (8.02%) 22 |
| Type 2 diabetes mellitus | Additional description: Type 2 diabetes mellitus | | |
| subjects affected / exposed occurrences (all) | 0 / 228 (0.00%) 0 | 0 / 216 (0.00%) 0 | 1 / 237 (0.42%) 1 |
| Vitamin D deficiency | Additional description: Vitamin D deficiency | | |
| subjects affected / exposed occurrences (all) | 2 / 228 (0.88%) 2 | 1 / 216 (0.46%) 1 | 2 / 237 (0.84%) 2 |
| Vitamin B12 deficiency | Additional description: Vitamin B12 deficiency | | |
| subjects affected / exposed occurrences (all) | 3 / 228 (1.32%) 3 | 1 / 216 (0.46%) 1 | 0 / 237 (0.00%) 0 |

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|---|---|--|--|
| Non-serious adverse events | GIVe arm | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 231 / 231 (100.00%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma of colon | Additional description: Adenocarcinoma of colon | | |
| subjects affected / exposed occurrences (all) | 1 / 231 (0.43%) 1 | | |
| Anogenital warts | Additional description: Anogenital warts | | |
| subjects affected / exposed occurrences (all) | 0 / 231 (0.00%) 0 | | |
| Angiomyolipoma | Additional description: Angiomyolipoma | | |
| subjects affected / exposed occurrences (all) | 0 / 231 (0.00%) 0 | | |
| Basal cell carcinoma | Additional description: Basal cell carcinoma | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Benign soft tissue neoplasm | Additional description: Benign soft tissue neoplasm | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Bowen's disease | Additional description: Bowen's disease | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Choroid melanoma | Additional description: Choroid melanoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Colon adenoma | Additional description: Colon adenoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Colon cancer | Additional description: Colon cancer | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cutaneous T-cell lymphoma | Additional description: Cutaneous T-cell lymphoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythroplasia | Additional description: Erythroplasia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Fibroma | Additional description: Fibroma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemangioma | Additional description: Haemangioma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Haemangioma of liver | Additional description: Haemangioma of liver | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Keratoacanthoma | Additional description: Keratoacanthoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lipoma | Additional description: Lipoma | | |

| | | | |
|-----------------------------|--|--|--|
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Malignant melanoma | Additional description: Malignant melanoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Melanocytic naevus | Additional description: Melanocytic naevus | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Malignant melanoma in situ | Additional description: Malignant melanoma in situ | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Myelodysplastic syndrome | Additional description: Myelodysplastic syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Myelofibrosis | Additional description: Myelofibrosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Non-small cell lung cancer | Additional description: Non-small cell lung cancer | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Papilloma | Additional description: Papilloma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Plasmacytoma | Additional description: Plasmacytoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Polycythaemia vera | Additional description: Polycythaemia vera | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Prostate cancer | Additional description: Prostate cancer | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Schwannoma | Additional description: Schwannoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seborrhoeic keratosis | Additional description: Seborrhoeic keratosis | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Richter's syndrome | Additional description: Richter's syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Skin papilloma | Additional description: Skin papilloma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Squamous cell carcinoma | Additional description: Squamous cell carcinoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| T-cell lymphoma | Additional description: T-cell lymphoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Thyroid neoplasm | Additional description: Thyroid neoplasm | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Transitional cell carcinoma | Additional description: Transitional cell carcinoma | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular disorders | | | |
| Aortic aneurysm | Additional description: Aortic aneurysm | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aortic dilatation | Additional description: Aortic dilatation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arteriosclerosis | Additional description: Arteriosclerosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Blood pressure fluctuation | Additional description: Blood pressure fluctuation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blue toe syndrome | Additional description: Blue toe syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |

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|---|---|--|
| Circulatory collapse subjects affected / exposed occurrences (all) | Additional description: Circulatory collapse | |
| | 0 / 231 (0.00%) 0 | |
| Deep vein thrombosis subjects affected / exposed occurrences (all) | Additional description: Deep vein thrombosis | |
| | 0 / 231 (0.00%) 0 | |
| Embolism subjects affected / exposed occurrences (all) | Additional description: Embolism | |
| | 1 / 231 (0.43%) 1 | |
| Flushing subjects affected / exposed occurrences (all) | Additional description: Flushing | |
| | 2 / 231 (0.87%) 2 | |
| Gestational hypertension subjects affected / exposed occurrences (all) | Additional description: Gestational hypertension | |
| | 1 / 231 (0.43%) 1 | |
| Haematoma subjects affected / exposed occurrences (all) | Additional description: Haematoma | |
| | 29 / 231 (12.55%) 35 | |
| Haemorrhage subjects affected / exposed occurrences (all) | Additional description: Haemorrhage | |
| | 1 / 231 (0.43%) 1 | |
| Hot flush subjects affected / exposed occurrences (all) | Additional description: Hot flush | |
| | 9 / 231 (3.90%) 9 | |
| Hypotension subjects affected / exposed occurrences (all) | Additional description: Hypotension | |
| | 4 / 231 (1.73%) 4 | |
| Hypertensive crisis subjects affected / exposed occurrences (all) | Additional description: Hypertensive crisis | |
| | 0 / 231 (0.00%) 0 | |
| Hypertension subjects affected / exposed occurrences (all) | Additional description: Hypertension | |
| | 29 / 231 (12.55%) 32 | |
| Peripheral arterial occlusive disease subjects affected / exposed occurrences (all) | Additional description: Peripheral arterial occlusive disease | |
| | 0 / 231 (0.00%) 0 | |

| | | |
|--|--|--|
| Peripheral coldness subjects affected / exposed occurrences (all) | Additional description: Peripheral coldness | |
| | 1 / 231 (0.43%) 1 | |
| Phlebitis subjects affected / exposed occurrences (all) | Additional description: Phlebitis | |
| | 0 / 231 (0.00%) 0 | |
| Poor peripheral circulation subjects affected / exposed occurrences (all) | Additional description: Poor peripheral circulation | |
| | 1 / 231 (0.43%) 1 | |
| Raynaud's phenomenon subjects affected / exposed occurrences (all) | Additional description: Raynaud's phenomenon | |
| | 0 / 231 (0.00%) 0 | |
| Thrombophlebitis subjects affected / exposed occurrences (all) | Additional description: Thrombophlebitis | |
| | 1 / 231 (0.43%) 2 | |
| Thrombophlebitis superficial subjects affected / exposed occurrences (all) | Additional description: Thrombophlebitis superficial | |
| | 1 / 231 (0.43%) 1 | |
| Thrombosis subjects affected / exposed occurrences (all) | Additional description: Thrombosis | |
| | 1 / 231 (0.43%) 1 | |
| Varicose vein subjects affected / exposed occurrences (all) | Additional description: Varicose vein | |
| | 0 / 231 (0.00%) 0 | |
| Vasculitis subjects affected / exposed occurrences (all) | Additional description: Vasculitis | |
| | 0 / 231 (0.00%) 0 | |
| Venous thrombosis subjects affected / exposed occurrences (all) | Additional description: Venous thrombosis | |
| | 1 / 231 (0.43%) 1 | |
| Surgical and medical procedures Cranial remodelling therapy subjects affected / exposed occurrences (all) | Additional description: Cranial remodelling therapy | |
| | 0 / 231 (0.00%) 0 | |
| | Additional description: Endodontic procedure | |
| Endodontic procedure | | |

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|--|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint irrigation | Additional description: Joint irrigation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mastoidectomy | Additional description: Mastoidectomy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Polypectomy | Additional description: Polypectomy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth extraction | Additional description: Tooth extraction | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 3 | | |
| General disorders and administration site conditions | | | |
| Axillary pain | Additional description: Axillary pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Asthenia | Additional description: Asthenia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 3 | | |
| Catheter site extravasation | Additional description: Catheter site extravasation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Catheter site pain | Additional description: Catheter site pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Catheter site swelling | Additional description: Catheter site swelling | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chest discomfort | Additional description: Chest discomfort | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Chest pain | Additional description: Chest pain | | |

| | | | |
|---------------------------------------|---|--|--|
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 5 | | |
| Chills | Additional description: Chills | | |
| subjects affected / exposed | 14 / 231 (6.06%) | | |
| occurrences (all) | 14 | | |
| Catheter site bruise | Additional description: Catheter site bruise | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Cyst | Additional description: Cyst | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Drug intolerance | Additional description: Drug intolerance | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Discomfort | Additional description: Discomfort | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Extravasation | Additional description: Extravasation | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Face oedema | Additional description: Face oedema | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Fatigue | Additional description: Fatigue | | |
| subjects affected / exposed | 80 / 231 (34.63%) | | |
| occurrences (all) | 87 | | |
| Feeling cold | Additional description: Feeling cold | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gait disturbance | Additional description: Gait disturbance | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Feeling hot | Additional description: Feeling hot | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| General physical health deterioration | Additional description: General physical health deterioration | | |

| | | | |
|-----------------------------|---|--|--|
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Inflammation | Additional description: Inflammation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Induration | Additional description: Induration | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Influenza like illness | Additional description: Influenza like illness | | |
| subjects affected / exposed | 19 / 231 (8.23%) | | |
| occurrences (all) | 21 | | |
| Infusion site extravasation | Additional description: Infusion site extravasation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injection site pain | Additional description: Injection site pain | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injection site reaction | Additional description: Injection site reaction | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injection site swelling | Additional description: Injection site swelling | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Malaise | Additional description: Malaise | | |
| subjects affected / exposed | 9 / 231 (3.90%) | | |
| occurrences (all) | 12 | | |
| Mass | Additional description: Mass | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mucosal inflammation | Additional description: Mucosal inflammation | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 6 | | |
| Non-cardiac chest pain | Additional description: Non-cardiac chest pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Oedema | Additional description: Oedema | | |

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|---|---|--|--|
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 6 | | |
| Oedema peripheral | Additional description: Oedema peripheral | | |
| subjects affected / exposed | 12 / 231 (5.19%) | | |
| occurrences (all) | 12 | | |
| Pain | Additional description: Pain | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Papillitis | Additional description: Papillitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral oedema neonatal | Additional description: Peripheral oedema neonatal | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Peripheral swelling | Additional description: Peripheral swelling | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 7 | | |
| Pyrexia | Additional description: Pyrexia | | |
| subjects affected / exposed | 26 / 231 (11.26%) | | |
| occurrences (all) | 30 | | |
| Swelling | Additional description: Swelling | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Systemic inflammatory response syndrome | Additional description: Systemic inflammatory response syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Thirst | Additional description: Thirst | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tissue infiltration | Additional description: Tissue infiltration | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Immune system disorders | | | |
| Anaphylactic reaction | Additional description: Anaphylactic reaction | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Autoimmune disorder | Additional description: Autoimmune disorder | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cytokine release syndrome | Additional description: Cytokine release syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Drug hypersensitivity | Additional description: Drug hypersensitivity | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypersensitivity | Additional description: Hypersensitivity | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 5 | | |
| Hypogammaglobulinaemia | Additional description: Hypogammaglobulinaemia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Immune reconstitution inflammatory syndrome | Additional description: Immune reconstitution inflammatory syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Immunodeficiency | Additional description: Immunodeficiency | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seasonal allergy | Additional description: Seasonal allergy | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Secondary immunodeficiency | Additional description: Secondary immunodeficiency | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Selective IgG subclass deficiency | Additional description: Selective IgG subclass deficiency | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reproductive system and breast disorders | | | |

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|--|--|--|
| Balanoposthitis subjects affected / exposed occurrences (all) | Additional description: Balanoposthitis | |
| | 0 / 231 (0.00%) 0 | |
| Benign prostatic hyperplasia subjects affected / exposed occurrences (all) | Additional description: Benign prostatic hyperplasia | |
| | 1 / 231 (0.43%) 1 | |
| Breast induration subjects affected / exposed occurrences (all) | Additional description: Breast induration | |
| | 0 / 231 (0.00%) 0 | |
| Breast pain subjects affected / exposed occurrences (all) | Additional description: Breast pain | |
| | 3 / 231 (1.30%) 3 | |
| Dyspareunia subjects affected / exposed occurrences (all) | Additional description: Dyspareunia | |
| | 1 / 231 (0.43%) 1 | |
| Endometriosis subjects affected / exposed occurrences (all) | Additional description: Endometriosis | |
| | 0 / 231 (0.00%) 0 | |
| Erectile dysfunction subjects affected / exposed occurrences (all) | Additional description: Erectile dysfunction | |
| | 2 / 231 (0.87%) 2 | |
| Haemospermia subjects affected / exposed occurrences (all) | Additional description: Haemospermia | |
| | 2 / 231 (0.87%) 2 | |
| Hypomenorrhoea subjects affected / exposed occurrences (all) | Additional description: Hypomenorrhoea | |
| | 0 / 231 (0.00%) 0 | |
| Menopausal symptoms subjects affected / exposed occurrences (all) | Additional description: Menopausal symptoms | |
| | 1 / 231 (0.43%) 1 | |
| Menorrhagia subjects affected / exposed occurrences (all) | Additional description: Menorrhagia | |
| | 2 / 231 (0.87%) 2 | |
| Menstruation irregular subjects affected / exposed occurrences (all) | Additional description: Menstruation irregular | |
| | 0 / 231 (0.00%) 0 | |

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|---|---|--|
| Nipple pain subjects affected / exposed occurrences (all) | Additional description: Nipple pain | |
| | 0 / 231 (0.00%) 0 | |
| Ovarian hyperfunction subjects affected / exposed occurrences (all) | Additional description: Ovarian hyperfunction | |
| | 0 / 231 (0.00%) 0 | |
| Penis disorder subjects affected / exposed occurrences (all) | Additional description: Penis disorder | |
| | 2 / 231 (0.87%) 2 | |
| Pelvic pain subjects affected / exposed occurrences (all) | Additional description: Pelvic pain | |
| | 0 / 231 (0.00%) 0 | |
| Prostatic hypoplasia subjects affected / exposed occurrences (all) | Additional description: Prostatic hypoplasia | |
| | 0 / 231 (0.00%) 0 | |
| Prostatitis subjects affected / exposed occurrences (all) | Additional description: Prostatitis | |
| | 1 / 231 (0.43%) 1 | |
| Scrotal oedema subjects affected / exposed occurrences (all) | Additional description: Scrotal oedema | |
| | 1 / 231 (0.43%) 1 | |
| Testicular disorder subjects affected / exposed occurrences (all) | Additional description: Testicular disorder | |
| | 0 / 231 (0.00%) 0 | |
| Testicular pain subjects affected / exposed occurrences (all) | Additional description: Testicular pain | |
| | 1 / 231 (0.43%) 1 | |
| Vaginal haemorrhage subjects affected / exposed occurrences (all) | Additional description: Vaginal haemorrhage | |
| | 3 / 231 (1.30%) 3 | |
| Vaginal discharge subjects affected / exposed occurrences (all) | Additional description: Vaginal discharge | |
| | 1 / 231 (0.43%) 1 | |
| Vulvovaginal pruritus subjects affected / exposed occurrences (all) | Additional description: Vulvovaginal pruritus | |
| | 0 / 231 (0.00%) 0 | |

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|---|---|--|--|
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | Additional description: Asthma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Bronchospasm | Additional description: Bronchospasm | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Chronic obstructive pulmonary disease | Additional description: Chronic obstructive pulmonary disease | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Cough | Additional description: Cough | | |
| subjects affected / exposed | 37 / 231 (16.02%) | | |
| occurrences (all) | 43 | | |
| Dysaesthesia pharynx | Additional description: Dysaesthesia pharynx | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysphonia | Additional description: Dysphonia | | |
| subjects affected / exposed | 7 / 231 (3.03%) | | |
| occurrences (all) | 7 | | |
| Dyspnoea | Additional description: Dyspnoea | | |
| subjects affected / exposed | 18 / 231 (7.79%) | | |
| occurrences (all) | 18 | | |
| Dyspnoea exertional | Additional description: Dyspnoea exertional | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Epistaxis | Additional description: Epistaxis | | |
| subjects affected / exposed | 22 / 231 (9.52%) | | |
| occurrences (all) | 27 | | |
| Haemoptysis | Additional description: Haemoptysis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hiccups | Additional description: Hiccups | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Hyperventilation | Additional description: Hyperventilation | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Interstitial lung disease | Additional description: Interstitial lung disease | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Laryngeal inflammation | Additional description: Laryngeal inflammation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal congestion | Additional description: Nasal congestion | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal discomfort | Additional description: Nasal discomfort | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Nasal dryness | Additional description: Nasal dryness | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Nasal inflammation | Additional description: Nasal inflammation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal obstruction | Additional description: Nasal obstruction | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal ulcer | Additional description: Nasal ulcer | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Oropharyngeal pain | Additional description: Oropharyngeal pain | | |
| subjects affected / exposed | 14 / 231 (6.06%) | | |
| occurrences (all) | 15 | | |
| Pharyngeal inflammation | Additional description: Pharyngeal inflammation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pleural effusion | Additional description: Pleural effusion | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonitis | Additional description: Pneumonitis | | |

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|-----------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Productive cough | Additional description: Productive cough | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 6 | | |
| Pulmonary embolism | Additional description: Pulmonary embolism | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Pulmonary hypertension | Additional description: Pulmonary hypertension | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary pain | Additional description: Pulmonary pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Rhinitis allergic | Additional description: Rhinitis allergic | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Respiratory alkalosis | Additional description: Respiratory alkalosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Rhinorrhoea | Additional description: Rhinorrhoea | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Sinus pain | Additional description: Sinus pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Sleep apnoea syndrome | Additional description: Sleep apnoea syndrome | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tachypnoea | Additional description: Tachypnoea | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Throat clearing | Additional description: Throat clearing | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Throat irritation | Additional description: Throat irritation | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 5 | | |
| Throatache | Additional description: Throatache | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Upper-airway cough syndrome | Additional description: Upper-airway cough syndrome | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wheezing | Additional description: Wheezing | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psychiatric disorders | | | |
| Abnormal dreams | Additional description: Abnormal dreams | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Agitation | Additional description: Agitation | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Aggression | Additional description: Aggression | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Adjustment disorder | Additional description: Adjustment disorder | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Anxiety | Additional description: Anxiety | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Apathy | Additional description: Apathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bruxism | Additional description: Bruxism | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Confusional state | Additional description: Confusional state | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |

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|-----------------------------|--|--|
| Depression | Additional description: Depression | |
| subjects affected / exposed | 7 / 231 (3.03%) | |
| occurrences (all) | 7 | |
| Delirium | Additional description: Delirium | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Depressed mood | Additional description: Depressed mood | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Disorientation | Additional description: Disorientation | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Hallucination | Additional description: Hallucination | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Hyperarousal | Additional description: Hyperarousal | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Illusion | Additional description: Illusion | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Insomnia | Additional description: Insomnia | |
| subjects affected / exposed | 10 / 231 (4.33%) | |
| occurrences (all) | 11 | |
| Irritability | Additional description: Irritability | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Panic attack | Additional description: Panic attack | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Restlessness | Additional description: Restlessness | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Sleep disorder | Additional description: Sleep disorder | |
| subjects affected / exposed | 4 / 231 (1.73%) | |
| occurrences (all) | 4 | |

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|---|---|--|--|
| Somnambulism subjects affected / exposed occurrences (all) | Additional description: Somnambulism | | |
| | 0 / 231 (0.00%) | | |
| Stress subjects affected / exposed occurrences (all) | Additional description: Stress | | |
| | 0 / 231 (0.00%) | | |
| Investigations | | | |
| Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all) | Additional description: Activated partial thromboplastin time prolonged | | |
| | 1 / 231 (0.43%) | | |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | Additional description: Alanine aminotransferase increased | | |
| | 9 / 231 (3.90%) | | |
| Amylase increased subjects affected / exposed occurrences (all) | Additional description: Amylase increased | | |
| | 0 / 231 (0.00%) | | |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | Additional description: Aspartate aminotransferase increased | | |
| | 10 / 231 (4.33%) | | |
| Blood immunoglobulin G decreased subjects affected / exposed occurrences (all) | Additional description: Blood immunoglobulin G decreased | | |
| | 2 / 231 (0.87%) | | |
| Basophil count decreased subjects affected / exposed occurrences (all) | Additional description: Basophil count decreased | | |
| | 0 / 231 (0.00%) | | |
| Blood alkaline phosphatase increased subjects affected / exposed occurrences (all) | Additional description: Blood alkaline phosphatase increased | | |
| | 4 / 231 (1.73%) | | |
| Blood bilirubin increased subjects affected / exposed occurrences (all) | Additional description: Blood bilirubin increased | | |
| | 9 / 231 (3.90%) | | |
| Blood calcium decreased subjects affected / exposed occurrences (all) | Additional description: Blood calcium decreased | | |
| | 1 / 231 (0.43%) | | |
| Blood chloride increased | Additional description: Blood chloride increased | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood creatine increased | Additional description: Blood creatine increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood creatinine increased | Additional description: Blood creatinine increased | | |
| subjects affected / exposed | 7 / 231 (3.03%) | | |
| occurrences (all) | 7 | | |
| Blood glucose increased | Additional description: Blood glucose increased | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Blood immunoglobulin M decreased | Additional description: Blood immunoglobulin M decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood lactate dehydrogenase increased | Additional description: Blood lactate dehydrogenase increased | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Blood phosphorus increased | Additional description: Blood phosphorus increased | | |
| subjects affected / exposed | 9 / 231 (3.90%) | | |
| occurrences (all) | 13 | | |
| Blood potassium decreased | Additional description: Blood potassium decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood potassium increased | Additional description: Blood potassium increased | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Blood pressure increased | Additional description: Blood pressure increased | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Blood thyroid stimulating hormone increased | Additional description: Blood thyroid stimulating hormone increased | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Blood urea increased | Additional description: Blood urea increased | | |

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|------------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Blood uric acid decreased | Additional description: Blood uric acid decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood uric acid increased | Additional description: Blood uric acid increased | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 8 | | |
| Body temperature increased | Additional description: Body temperature increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood iron decreased | Additional description: Blood iron decreased | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Cardiac murmur | Additional description: Cardiac murmur | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Bronchoscopy | Additional description: Bronchoscopy | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| C-reactive protein | Additional description: C-reactive protein | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| C-reactive protein increased | Additional description: C-reactive protein increased | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 5 | | |
| Cortisol decreased | Additional description: Cortisol decreased | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Enterococcus test positive | Additional description: Enterococcus test positive | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Eosinophil count decreased | Additional description: Eosinophil count decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Free haemoglobin present | Additional description: Free haemoglobin present | | |

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|---|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Gamma-glutamyltransferase increased | Additional description: Gamma-glutamyltransferase increased | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 12 | | |
| Glomerular filtration rate decreased | Additional description: Glomerular filtration rate decreased | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Heart rate irregular | Additional description: Heart rate irregular | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatic enzyme abnormal | Additional description: Hepatic enzyme abnormal | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Hepatic enzyme increased | Additional description: Hepatic enzyme increased | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Hepatitis B DNA increased | Additional description: Hepatitis B DNA increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immunoglobulins decreased | Additional description: Immunoglobulins decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Inflammatory marker increased | Additional description: Inflammatory marker increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| International normalised ratio increased | Additional description: International normalised ratio increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intraocular pressure increased | Additional description: Intraocular pressure increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Left ventricular end-diastolic pressure decreased | Additional description: Left ventricular end-diastolic pressure decreased | | |

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|---|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lipase increased | Additional description: Lipase increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Liver function test increased | Additional description: Liver function test increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Monocyte count decreased | Additional description: Monocyte count decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myocardial necrosis marker increased | Additional description: Myocardial necrosis marker increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| N-terminal prohormone brain natriuretic peptide increased | Additional description: N-terminal prohormone brain natriuretic peptide increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neutrophil count decreased | Additional description: Neutrophil count decreased | | |
| subjects affected / exposed | 33 / 231 (14.29%) | | |
| occurrences (all) | 48 | | |
| Platelet count decreased | Additional description: Platelet count decreased | | |
| subjects affected / exposed | 22 / 231 (9.52%) | | |
| occurrences (all) | 31 | | |
| Procalcitonin increased | Additional description: Procalcitonin increased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reticulocyte count decreased | Additional description: Reticulocyte count decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| SARS-CoV-2 test positive | Additional description: SARS-CoV-2 test positive | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Serum ferritin decreased | Additional description: Serum ferritin decreased | | |

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|--|--|--|--|
| subjects affected / exposed occurrences (all) | 0 / 231 (0.00%) 0 | | |
| Transaminases increased | Additional description: Transaminases increased | | |
| subjects affected / exposed occurrences (all) | 1 / 231 (0.43%) 1 | | |
| Transferrin decreased | Additional description: Transferrin decreased | | |
| subjects affected / exposed occurrences (all) | 1 / 231 (0.43%) 1 | | |
| Vitamin B12 decreased | Additional description: Vitamin B12 decreased | | |
| subjects affected / exposed occurrences (all) | 1 / 231 (0.43%) 1 | | |
| Weight decreased | Additional description: Weight decreased | | |
| subjects affected / exposed occurrences (all) | 9 / 231 (3.90%) 9 | | |
| Weight increased | Additional description: Weight increased | | |
| subjects affected / exposed occurrences (all) | 7 / 231 (3.03%) 7 | | |
| White blood cell count decreased | Additional description: White blood cell count decreased | | |
| subjects affected / exposed occurrences (all) | 9 / 231 (3.90%) 18 | | |
| White blood cell count increased | Additional description: White blood cell count increased | | |
| subjects affected / exposed occurrences (all) | 0 / 231 (0.00%) 0 | | |
| Injury, poisoning and procedural complications | | | |
| Arthropod bite | Additional description: Arthropod bite | | |
| subjects affected / exposed occurrences (all) | 2 / 231 (0.87%) 2 | | |
| Animal bite | Additional description: Animal bite | | |
| subjects affected / exposed occurrences (all) | 2 / 231 (0.87%) 2 | | |
| Bone contusion | Additional description: Bone contusion | | |
| subjects affected / exposed occurrences (all) | 1 / 231 (0.43%) 1 | | |
| Chest injury | Additional description: Chest injury | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Clavicle fracture | Additional description: Clavicle fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Contusion | Additional description: Contusion | | |
| subjects affected / exposed | 10 / 231 (4.33%) | | |
| occurrences (all) | 11 | | |
| Ear canal injury | Additional description: Ear canal injury | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Epicondylitis | Additional description: Epicondylitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Face injury | Additional description: Face injury | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Fall | Additional description: Fall | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Foreign body in eye | Additional description: Foreign body in eye | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fracture | Additional description: Fracture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hand fracture | Additional description: Hand fracture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Head injury | Additional description: Head injury | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Infusion related reaction | Additional description: Infusion related reaction | | |
| subjects affected / exposed | 46 / 231 (19.91%) | | |
| occurrences (all) | 54 | | |
| Injury | Additional description: Injury | | |

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|--------------------------------|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ligament injury | Additional description: Ligament injury | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint capsule rupture | Additional description: Joint capsule rupture | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ligament sprain | Additional description: Ligament sprain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Limb injury | Additional description: Limb injury | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 3 | | |
| Mallet finger | Additional description: Mallet finger | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Meniscus injury | Additional description: Meniscus injury | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Mouth injury | Additional description: Mouth injury | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Multiple fractures | Additional description: Multiple fractures | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle strain | Additional description: Muscle strain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Nasal injury | Additional description: Nasal injury | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Paravenous drug administration | Additional description: Paravenous drug administration | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Procedural pain | Additional description: Procedural pain | | |

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|------------------------------|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post-traumatic neck syndrome | Additional description: Post-traumatic neck syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Road traffic accident | Additional description: Road traffic accident | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Scar | Additional description: Scar | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin abrasion | Additional description: Skin abrasion | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Skin wound | Additional description: Skin wound | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Spinal compression fracture | Additional description: Spinal compression fracture | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 6 | | |
| Spinal fracture | Additional description: Spinal fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Tendon rupture | Additional description: Tendon rupture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Thermal burn | Additional description: Thermal burn | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Thoracic vertebral fracture | Additional description: Thoracic vertebral fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Tooth injury | Additional description: Tooth injury | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Transfusion reaction | Additional description: Transfusion reaction | | |

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|--|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Traumatic ear amputation | Additional description: Traumatic ear amputation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Traumatic haematoma | Additional description: Traumatic haematoma | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Vascular access complication | Additional description: Vascular access complication | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wrist fracture | Additional description: Wrist fracture | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Wound | Additional description: Wound | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 5 | | |
| Wound complication | Additional description: Wound complication | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital, familial and genetic disorders | | | |
| Cryptorchism | Additional description: Cryptorchism | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Glycogen storage disease type I | Additional description: Glycogen storage disease type I | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hydrocele | Additional description: Hydrocele | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Ichthyosis | Additional description: Ichthyosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Phimosis | Additional description: Phimosis | | |

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|--------------------------------------|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac disorders | | | |
| Acute coronary syndrome | Additional description: Acute coronary syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Angina pectoris | Additional description: Angina pectoris | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Arteriosclerosis coronary artery | Additional description: Arteriosclerosis coronary artery | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Arrhythmia | Additional description: Arrhythmia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Atrial fibrillation | Additional description: Atrial fibrillation | | |
| subjects affected / exposed | 17 / 231 (7.36%) | | |
| occurrences (all) | 19 | | |
| Atrial flutter | Additional description: Atrial flutter | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Atrial thrombosis | Additional description: Atrial thrombosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Atrioventricular block second degree | Additional description: Atrioventricular block second degree | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bradycardia | Additional description: Bradycardia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bundle branch block right | Additional description: Bundle branch block right | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac discomfort | Additional description: Cardiac discomfort | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |

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|------------------------------|--|--|
| Cardiac failure | Additional description: Cardiac failure | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Cardiovascular disorder | Additional description: Cardiovascular disorder | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Coronary artery disease | Additional description: Coronary artery disease | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Coronary artery stenosis | Additional description: Coronary artery stenosis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Extrasystoles | Additional description: Extrasystoles | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Hypertensive heart disease | Additional description: Hypertensive heart disease | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Myocardial ischaemia | Additional description: Myocardial ischaemia | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Palpitations | Additional description: Palpitations | |
| subjects affected / exposed | 10 / 231 (4.33%) | |
| occurrences (all) | 13 | |
| Pericardial effusion | Additional description: Pericardial effusion | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Right ventricular failure | Additional description: Right ventricular failure | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Sinus tachycardia | Additional description: Sinus tachycardia | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Supraventricular tachycardia | Additional description: Supraventricular tachycardia | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |

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|---|---|--|--|
| Tachycardia subjects affected / exposed occurrences (all) | Additional description: Tachycardia | | |
| | 3 / 231 (1.30%) | | |
| | 3 | | |
| Tachycardia paroxysmal subjects affected / exposed occurrences (all) | Additional description: Tachycardia paroxysmal | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Ventricular extrasystoles subjects affected / exposed occurrences (all) | Additional description: Ventricular extrasystoles | | |
| | 1 / 231 (0.43%) | | |
| | 3 | | |
| Nervous system disorders | | | |
| Ageusia subjects affected / exposed occurrences (all) | Additional description: Ageusia | | |
| | 2 / 231 (0.87%) | | |
| | 2 | | |
| Amnesia subjects affected / exposed occurrences (all) | Additional description: Amnesia | | |
| | 2 / 231 (0.87%) | | |
| | 2 | | |
| Aphasia subjects affected / exposed occurrences (all) | Additional description: Aphasia | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Ataxia subjects affected / exposed occurrences (all) | Additional description: Ataxia | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Balance disorder subjects affected / exposed occurrences (all) | Additional description: Balance disorder | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Burning sensation subjects affected / exposed occurrences (all) | Additional description: Burning sensation | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Carpal tunnel syndrome subjects affected / exposed occurrences (all) | Additional description: Carpal tunnel syndrome | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Cervicobrachial syndrome subjects affected / exposed occurrences (all) | Additional description: Cervicobrachial syndrome | | |
| | 2 / 231 (0.87%) | | |
| | 2 | | |
| Carotid artery stenosis | Additional description: Carotid artery stenosis | | |
| | | | |
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|----------------------------------|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Concentration impairment | Additional description: Concentration impairment | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cognitive disorder | Additional description: Cognitive disorder | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cubital tunnel syndrome | Additional description: Cubital tunnel syndrome | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Depressed level of consciousness | Additional description: Depressed level of consciousness | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Disturbance in attention | Additional description: Disturbance in attention | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 6 | | |
| Dizziness | Additional description: Dizziness | | |
| subjects affected / exposed | 23 / 231 (9.96%) | | |
| occurrences (all) | 24 | | |
| Dizziness postural | Additional description: Dizziness postural | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysaesthesia | Additional description: Dysaesthesia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Dysgeusia | Additional description: Dysgeusia | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 4 | | |
| Facial paralysis | Additional description: Facial paralysis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Formication | Additional description: Formication | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hand-arm vibration syndrome | Additional description: Hand-arm vibration syndrome | | |

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|-----------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Head discomfort | Additional description: Head discomfort | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Headache | Additional description: Headache | | |
| subjects affected / exposed | 39 / 231 (16.88%) | | |
| occurrences (all) | 52 | | |
| Hypoaesthesia | Additional description: Hypoaesthesia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Hypertonia | Additional description: Hypertonia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Hypotonia | Additional description: Hypotonia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Intention tremor | Additional description: Intention tremor | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lumbar radiculopathy | Additional description: Lumbar radiculopathy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Memory impairment | Additional description: Memory impairment | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 5 | | |
| Mental impairment | Additional description: Mental impairment | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Migraine | Additional description: Migraine | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Muscle spasticity | Additional description: Muscle spasticity | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neuromuscular blockade | Additional description: Neuromuscular blockade | | |

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|-------------------------------|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Olfactory nerve disorder | Additional description: Olfactory nerve disorder | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Neuropathy peripheral | Additional description: Neuropathy peripheral | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 6 | | |
| Orthostatic intolerance | Additional description: Orthostatic intolerance | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Paraesthesia | Additional description: Paraesthesia | | |
| subjects affected / exposed | 9 / 231 (3.90%) | | |
| occurrences (all) | 10 | | |
| Parkinson's disease | Additional description: Parkinson's disease | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Parosmia | Additional description: Parosmia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral motor neuropathy | Additional description: Peripheral motor neuropathy | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Peripheral sensory neuropathy | Additional description: Peripheral sensory neuropathy | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Polyneuropathy | Additional description: Polyneuropathy | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Post herpetic neuralgia | Additional description: Post herpetic neuralgia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Presyncope | Additional description: Presyncope | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 5 | | |
| Restless legs syndrome | Additional description: Restless legs syndrome | | |

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|--------------------------------------|--|--|--|
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Sciatica | Additional description: Sciatica | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Sensory disturbance | Additional description: Sensory disturbance | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Syncope | Additional description: Syncope | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Somnolence | Additional description: Somnolence | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Taste disorder | Additional description: Taste disorder | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Transient global amnesia | Additional description: Transient global amnesia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 2 | | |
| Tremor | Additional description: Tremor | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Trigeminal neuralgia | Additional description: Trigeminal neuralgia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Visual field defect | Additional description: Visual field defect | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood and lymphatic system disorders | | | |
| Agranulocytosis | Additional description: Agranulocytosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Anaemia | Additional description: Anaemia | | |
| subjects affected / exposed | 20 / 231 (8.66%) | | |
| occurrences (all) | 25 | | |

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|---|---|--|
| Autoimmune haemolytic anaemia subjects affected / exposed occurrences (all) | Additional description: Autoimmune haemolytic anaemia | |
| | 1 / 231 (0.43%) 2 | |
| Bicytopenia subjects affected / exposed occurrences (all) | Additional description: Bicytopenia | |
| | 0 / 231 (0.00%) 0 | |
| Eosinophilia subjects affected / exposed occurrences (all) | Additional description: Eosinophilia | |
| | 0 / 231 (0.00%) 0 | |
| Febrile neutropenia subjects affected / exposed occurrences (all) | Additional description: Febrile neutropenia | |
| | 2 / 231 (0.87%) 2 | |
| Granulocytopenia subjects affected / exposed occurrences (all) | Additional description: Granulocytopenia | |
| | 1 / 231 (0.43%) 1 | |
| Haemolysis subjects affected / exposed occurrences (all) | Additional description: Haemolysis | |
| | 0 / 231 (0.00%) 0 | |
| Haemorrhagic diathesis subjects affected / exposed occurrences (all) | Additional description: Haemorrhagic diathesis | |
| | 2 / 231 (0.87%) 2 | |
| Hypoglobulinaemia subjects affected / exposed occurrences (all) | Additional description: Hypoglobulinaemia | |
| | 2 / 231 (0.87%) 2 | |
| Immune thrombocytopenia subjects affected / exposed occurrences (all) | Additional description: Immune thrombocytopenia | |
| | 0 / 231 (0.00%) 0 | |
| Iron deficiency anaemia subjects affected / exposed occurrences (all) | Additional description: Iron deficiency anaemia | |
| | 4 / 231 (1.73%) 4 | |
| Leukocytosis subjects affected / exposed occurrences (all) | Additional description: Leukocytosis | |
| | 2 / 231 (0.87%) 2 | |
| Leukopenia subjects affected / exposed occurrences (all) | Additional description: Leukopenia | |
| | 17 / 231 (7.36%) 27 | |

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|--|---|--|
| Lymph node pain subjects affected / exposed occurrences (all) | Additional description: Lymph node pain | |
| | 1 / 231 (0.43%) 1 | |
| Lymphadenitis subjects affected / exposed occurrences (all) | Additional description: Lymphadenitis | |
| | 0 / 231 (0.00%) 0 | |
| Lymphadenopathy subjects affected / exposed occurrences (all) | Additional description: Lymphadenopathy | |
| | 1 / 231 (0.43%) 1 | |
| Macrocytosis subjects affected / exposed occurrences (all) | Additional description: Macrocytosis | |
| | 1 / 231 (0.43%) 1 | |
| Microcytic anaemia subjects affected / exposed occurrences (all) | Additional description: Microcytic anaemia | |
| | 1 / 231 (0.43%) 1 | |
| Neutropenia subjects affected / exposed occurrences (all) | Additional description: Neutropenia | |
| | 110 / 231 (47.62%) 237 | |
| Pancytopenia subjects affected / exposed occurrences (all) | Additional description: Pancytopenia | |
| | 2 / 231 (0.87%) 2 | |
| Reticulocytosis subjects affected / exposed occurrences (all) | Additional description: Reticulocytosis | |
| | 1 / 231 (0.43%) 1 | |
| Thrombocytopenia subjects affected / exposed occurrences (all) | Additional description: Thrombocytopenia | |
| | 52 / 231 (22.51%) 77 | |
| Ear and labyrinth disorders | | |
| | Additional description: Auditory disorder | |
| | 0 / 231 (0.00%) 0 | |
| | | |
| Deafness subjects affected / exposed occurrences (all) | Additional description: Deafness | |
| | 4 / 231 (1.73%) 4 | |
| Deafness unilateral | Additional description: Deafness unilateral | |
| | | |

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|-----------------------------|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear haemorrhage | Additional description: Ear haemorrhage | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Ear pain | Additional description: Ear pain | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Hypoacusis | Additional description: Hypoacusis | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Middle ear effusion | Additional description: Middle ear effusion | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Middle ear inflammation | Additional description: Middle ear inflammation | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Tinnitus | Additional description: Tinnitus | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Vertigo positional | Additional description: Vertigo positional | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vertigo | Additional description: Vertigo | | |
| subjects affected / exposed | 10 / 231 (4.33%) | | |
| occurrences (all) | 12 | | |
| Eye disorders | | | |
| Blepharitis | Additional description: Blepharitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Cataract | Additional description: Cataract | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Conjunctival haemorrhage | Additional description: Conjunctival haemorrhage | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |

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|-----------------------------|--|--|
| Corneal erosion | Additional description: Corneal erosion | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Diplopia | Additional description: Diplopia | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Dry eye | Additional description: Dry eye | |
| subjects affected / exposed | 6 / 231 (2.60%) | |
| occurrences (all) | 6 | |
| Erythema of eyelid | Additional description: Erythema of eyelid | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Exophthalmos | Additional description: Exophthalmos | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Eye haemorrhage | Additional description: Eye haemorrhage | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Eye inflammation | Additional description: Eye inflammation | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Eye irritation | Additional description: Eye irritation | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Eye oedema | Additional description: Eye oedema | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Eye pain | Additional description: Eye pain | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Eyelid haematoma | Additional description: Eyelid haematoma | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Eyelid oedema | Additional description: Eyelid oedema | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |

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|---|---|--|
| Eyelid ptosis subjects affected / exposed occurrences (all) | Additional description: Eyelid ptosis | |
| | 1 / 231 (0.43%) 1 | |
| Eye disorder subjects affected / exposed occurrences (all) | Additional description: Eye disorder | |
| | 0 / 231 (0.00%) 0 | |
| Glaucoma subjects affected / exposed occurrences (all) | Additional description: Glaucoma | |
| | 0 / 231 (0.00%) 0 | |
| Hyalosis asteroid subjects affected / exposed occurrences (all) | Additional description: Hyalosis asteroid | |
| | 0 / 231 (0.00%) 0 | |
| Lacrimation increased subjects affected / exposed occurrences (all) | Additional description: Lacrimation increased | |
| | 1 / 231 (0.43%) 1 | |
| Ocular hyperaemia subjects affected / exposed occurrences (all) | Additional description: Ocular hyperaemia | |
| | 2 / 231 (0.87%) 2 | |
| Ocular hypertension subjects affected / exposed occurrences (all) | Additional description: Ocular hypertension | |
| | 0 / 231 (0.00%) 0 | |
| Panophthalmitis subjects affected / exposed occurrences (all) | Additional description: Panophthalmitis | |
| | 0 / 231 (0.00%) 0 | |
| Periorbital oedema subjects affected / exposed occurrences (all) | Additional description: Periorbital oedema | |
| | 0 / 231 (0.00%) 0 | |
| Photophobia subjects affected / exposed occurrences (all) | Additional description: Photophobia | |
| | 1 / 231 (0.43%) 1 | |
| Retinal haemorrhage subjects affected / exposed occurrences (all) | Additional description: Retinal haemorrhage | |
| | 0 / 231 (0.00%) 0 | |
| Uveitis subjects affected / exposed occurrences (all) | Additional description: Uveitis | |
| | 1 / 231 (0.43%) 1 | |

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|--|--|--|
| Vitreous detachment subjects affected / exposed occurrences (all) | Additional description: Vitreous detachment | |
| | 0 / 231 (0.00%) | |
| | 0 | |
| | Additional description: Vitreous disorder | |
| | 0 / 231 (0.00%) | |
| Vitreous disorder subjects affected / exposed occurrences (all) | 0 | |
| | Additional description: Vitreous haemorrhage | |
| | 0 / 231 (0.00%) | |
| | 0 | |
| | Additional description: Visual impairment | |
| Visual impairment subjects affected / exposed occurrences (all) | 0 / 231 (0.00%) | |
| | 0 | |
| | Additional description: Vision blurred | |
| | 7 / 231 (3.03%) | |
| | 7 | |
| Gastrointestinal disorders Abdominal pain upper subjects affected / exposed occurrences (all) | Additional description: Abdominal pain upper | |
| | 21 / 231 (9.09%) | |
| | 23 | |
| | Additional description: Abdominal pain lower | |
| | 3 / 231 (1.30%) | |
| | 3 | |
| | Additional description: Abdominal pain | |
| | 15 / 231 (6.49%) | |
| | 15 | |
| | Additional description: Abdominal distension | |
| | 3 / 231 (1.30%) | |
| | 3 | |
| | Additional description: Abdominal discomfort | |
| | 6 / 231 (2.60%) | |
| | 7 | |
| Anal ulcer subjects affected / exposed occurrences (all) | Additional description: Anal ulcer | |
| | 1 / 231 (0.43%) | |
| | 1 | |
| Anal pruritus | Additional description: Anal pruritus | |

| | | | |
|-----------------------------|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal incontinence | Additional description: Anal incontinence | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Anal haemorrhage | Additional description: Anal haemorrhage | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Anal fissure | Additional description: Anal fissure | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Angular cheilitis | Additional description: Angular cheilitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Aphthous ulcer | Additional description: Aphthous ulcer | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Cheilitis | Additional description: Cheilitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Coeliac disease | Additional description: Coeliac disease | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Colitis | Additional description: Colitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Constipation | Additional description: Constipation | | |
| subjects affected / exposed | 29 / 231 (12.55%) | | |
| occurrences (all) | 32 | | |
| Crohn's disease | Additional description: Crohn's disease | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dental caries | Additional description: Dental caries | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Diarrhoea | Additional description: Diarrhoea | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 118 / 231 (51.08%) | | |
| occurrences (all) | 177 | | |
| Diarrhoea haemorrhagic | Additional description: Diarrhoea haemorrhagic | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Defaecation disorder | Additional description: Defaecation disorder | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diverticulum intestinal | Additional description: Diverticulum intestinal | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dry mouth | Additional description: Dry mouth | | |
| subjects affected / exposed | 10 / 231 (4.33%) | | |
| occurrences (all) | 10 | | |
| Dyspepsia | Additional description: Dyspepsia | | |
| subjects affected / exposed | 27 / 231 (11.69%) | | |
| occurrences (all) | 28 | | |
| Dysphagia | Additional description: Dysphagia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Enterovirus infection | Additional description: Enterovirus infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epigastric discomfort | Additional description: Epigastric discomfort | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Faeces discoloured | Additional description: Faeces discoloured | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastric haemorrhage | Additional description: Gastric haemorrhage | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Flatulence | Additional description: Flatulence | | |
| subjects affected / exposed | 8 / 231 (3.46%) | | |
| occurrences (all) | 8 | | |
| Food poisoning | Additional description: Food poisoning | | |

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|------------------------------------|--|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Frequent bowel movements | Additional description: Frequent bowel movements | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Giant cell epulis | Additional description: Giant cell epulis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Gingival bleeding | Additional description: Gingival bleeding | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Gastritis | Additional description: Gastritis | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Gastrointestinal haemorrhage | Additional description: Gastrointestinal haemorrhage | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal motility disorder | Additional description: Gastrointestinal motility disorder | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Gastrointestinal pain | Additional description: Gastrointestinal pain | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Gastrointestinal tract irritation | Additional description: Gastrointestinal tract irritation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrooesophageal reflux disease | Additional description: Gastrooesophageal reflux disease | | |
| subjects affected / exposed | 8 / 231 (3.46%) | | |
| occurrences (all) | 8 | | |
| Gingival discolouration | Additional description: Gingival discolouration | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Haemorrhoidal haemorrhage | Additional description: Haemorrhoidal haemorrhage | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haematochezia | Additional description: Haematochezia | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Haemorrhoids | Additional description: Haemorrhoids | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Inguinal hernia | Additional description: Inguinal hernia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Lip dry | Additional description: Lip dry | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Lip pain | Additional description: Lip pain | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Mouth haemorrhage | Additional description: Mouth haemorrhage | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Mouth ulceration | Additional description: Mouth ulceration | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Nausea | Additional description: Nausea | | |
| subjects affected / exposed | 77 / 231 (33.33%) | | |
| occurrences (all) | 100 | | |
| Odynophagia | Additional description: Odynophagia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Oesophagitis | Additional description: Oesophagitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Oral dysaesthesia | Additional description: Oral dysaesthesia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Oral mucosal blistering | Additional description: Oral mucosal blistering | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Oral mucosal erythema | Additional description: Oral mucosal erythema | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral pain | Additional description: Oral pain | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 3 | | |
| Paraesthesia oral | Additional description: Paraesthesia oral | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Periodontal disease | Additional description: Periodontal disease | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Proctalgia | Additional description: Proctalgia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rectal haemorrhage | Additional description: Rectal haemorrhage | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Rectal polyp | Additional description: Rectal polyp | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Salivary gland calculus | Additional description: Salivary gland calculus | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stomatitis | Additional description: Stomatitis | | |
| subjects affected / exposed | 12 / 231 (5.19%) | | |
| occurrences (all) | 14 | | |
| Tongue coated | Additional description: Tongue coated | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tongue discomfort | Additional description: Tongue discomfort | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Tongue disorder | Additional description: Tongue disorder | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Tongue dry | Additional description: Tongue dry | | |

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|-----------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Tooth loss | Additional description: Tooth loss | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Toothache | Additional description: Toothache | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 6 | | |
| Vomiting | Additional description: Vomiting | | |
| subjects affected / exposed | 24 / 231 (10.39%) | | |
| occurrences (all) | 36 | | |
| Hepatobiliary disorders | | | |
| Cholecystitis | Additional description: Cholecystitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Cholelithiasis | Additional description: Cholelithiasis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatic pain | Additional description: Hepatic pain | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatic steatosis | Additional description: Hepatic steatosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatotoxicity | Additional description: Hepatotoxicity | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperbilirubinaemia | Additional description: Hyperbilirubinaemia | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Liver disorder | Additional description: Liver disorder | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Portal vein dilatation | Additional description: Portal vein dilatation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |

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|--|--|--|--|
| Portal vein thrombosis subjects affected / exposed occurrences (all) | Additional description: Portal vein thrombosis | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| | Additional description: Actinic keratosis | | |
| Actinic keratosis subjects affected / exposed occurrences (all) | 3 / 231 (1.30%) | | |
| | 3 | | |
| | | | |
| Alopecia subjects affected / exposed occurrences (all) | Additional description: Alopecia | | |
| | 4 / 231 (1.73%) | | |
| | 4 | | |
| Blister subjects affected / exposed occurrences (all) | Additional description: Blister | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Blood blister subjects affected / exposed occurrences (all) | Additional description: Blood blister | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Cafe au lait spots subjects affected / exposed occurrences (all) | Additional description: Cafe au lait spots | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Dermatitis subjects affected / exposed occurrences (all) | Additional description: Dermatitis | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Dermatitis acneiform subjects affected / exposed occurrences (all) | Additional description: Dermatitis acneiform | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Dermatitis allergic subjects affected / exposed occurrences (all) | Additional description: Dermatitis allergic | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Dermatitis atopic subjects affected / exposed occurrences (all) | Additional description: Dermatitis atopic | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Dermatitis contact subjects affected / exposed occurrences (all) | Additional description: Dermatitis contact | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Dermatitis exfoliative | Additional description: Dermatitis exfoliative | | |
| | | | |

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|------------------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Dermatitis exfoliative generalised | Additional description: Dermatitis exfoliative generalised | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Decubitus ulcer | Additional description: Decubitus ulcer | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Drug eruption | Additional description: Drug eruption | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Dry skin | Additional description: Dry skin | | |
| subjects affected / exposed | 17 / 231 (7.36%) | | |
| occurrences (all) | 17 | | |
| Ecchymosis | Additional description: Ecchymosis | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 6 | | |
| Eczema | Additional description: Eczema | | |
| subjects affected / exposed | 12 / 231 (5.19%) | | |
| occurrences (all) | 12 | | |
| Eczema nummular | Additional description: Eczema nummular | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema | Additional description: Erythema | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Erythema nodosum | Additional description: Erythema nodosum | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Eosinophilic cellulitis | Additional description: Eosinophilic cellulitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema multiforme | Additional description: Erythema multiforme | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Hand dermatitis | Additional description: Hand dermatitis | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Hyperkeratosis | Additional description: Hyperkeratosis | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Hyperhidrosis | Additional description: Hyperhidrosis | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 6 | | |
| Hypertrichosis | Additional description: Hypertrichosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Intertrigo | Additional description: Intertrigo | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lentigo | Additional description: Lentigo | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lichen planus | Additional description: Lichen planus | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Neurodermatitis | Additional description: Neurodermatitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nail discolouration | Additional description: Nail discolouration | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nail dystrophy | Additional description: Nail dystrophy | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Nail pitting | Additional description: Nail pitting | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nail ridging | Additional description: Nail ridging | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Nail toxicity | Additional description: Nail toxicity | | |

| | | | |
|-----------------------------|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Night sweats | Additional description: Night sweats | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Onychoclasia | Additional description: Onychoclasia | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 6 | | |
| Onycholysis | Additional description: Onycholysis | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Papule | Additional description: Papule | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pemphigoid | Additional description: Pemphigoid | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Petechiae | Additional description: Petechiae | | |
| subjects affected / exposed | 12 / 231 (5.19%) | | |
| occurrences (all) | 17 | | |
| Pigmentation disorder | Additional description: Pigmentation disorder | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Rash generalised | Additional description: Rash generalised | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash erythematous | Additional description: Rash erythematous | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Pruritus | Additional description: Pruritus | | |
| subjects affected / exposed | 17 / 231 (7.36%) | | |
| occurrences (all) | 17 | | |
| Pruritus generalised | Additional description: Pruritus generalised | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psoriasis | Additional description: Psoriasis | | |

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|-----------------------------|--|--|--|
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 3 | | |
| Purpura | Additional description: Purpura | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Rash | Additional description: Rash | | |
| subjects affected / exposed | 37 / 231 (16.02%) | | |
| occurrences (all) | 49 | | |
| Rash macular | Additional description: Rash macular | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash maculo-papular | Additional description: Rash maculo-papular | | |
| subjects affected / exposed | 9 / 231 (3.90%) | | |
| occurrences (all) | 12 | | |
| Rash pruritic | Additional description: Rash pruritic | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rash papular | Additional description: Rash papular | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rosacea | Additional description: Rosacea | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Solar dermatitis | Additional description: Solar dermatitis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin burning sensation | Additional description: Skin burning sensation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin discolouration | Additional description: Skin discolouration | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin discomfort | Additional description: Skin discomfort | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Skin disorder | Additional description: Skin disorder | | |

| | | | |
|-----------------------------|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin fissures | Additional description: Skin fissures | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Skin hypopigmentation | Additional description: Skin hypopigmentation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin irritation | Additional description: Skin irritation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin lesion | Additional description: Skin lesion | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Skin mass | Additional description: Skin mass | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin ulcer | Additional description: Skin ulcer | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Suggillation | Additional description: Suggillation | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Telangiectasia | Additional description: Telangiectasia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Toxic skin eruption | Additional description: Toxic skin eruption | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urticaria | Additional description: Urticaria | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 2 | | |
| Renal and urinary disorders | | | |
| Acute kidney injury | Additional description: Acute kidney injury | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |

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|------------------------------|--|--|
| Chromaturia | Additional description: Chromaturia | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Chronic kidney disease | Additional description: Chronic kidney disease | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Cystitis noninfective | Additional description: Cystitis noninfective | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Dysuria | Additional description: Dysuria | |
| subjects affected / exposed | 3 / 231 (1.30%) | |
| occurrences (all) | 3 | |
| Haematuria | Additional description: Haematuria | |
| subjects affected / exposed | 8 / 231 (3.46%) | |
| occurrences (all) | 8 | |
| Hydronephrosis | Additional description: Hydronephrosis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Incontinence | Additional description: Incontinence | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Kidney congestion | Additional description: Kidney congestion | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Leukocyturia | Additional description: Leukocyturia | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Lower urinary tract symptoms | Additional description: Lower urinary tract symptoms | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Micturition disorder | Additional description: Micturition disorder | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Micturition urgency | Additional description: Micturition urgency | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |

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|-----------------------------|--|--|
| Nocturia | Additional description: Nocturia | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Pollakiuria | Additional description: Pollakiuria | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Polyuria | Additional description: Polyuria | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Renal colic | Additional description: Renal colic | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Renal cyst | Additional description: Renal cyst | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Renal failure | Additional description: Renal failure | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Renal pain | Additional description: Renal pain | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Strangury | Additional description: Strangury | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Urinary incontinence | Additional description: Urinary incontinence | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Urinary tract pain | Additional description: Urinary tract pain | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Urinary tract obstruction | Additional description: Urinary tract obstruction | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Urinary tract inflammation | Additional description: Urinary tract inflammation | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |

| | | | |
|---|---|--|--|
| Urinary retention subjects affected / exposed occurrences (all) | Additional description: Urinary retention | | |
| | 2 / 231 (0.87%) | | |
| | 2 | | |
| Urge incontinence subjects affected / exposed occurrences (all) | Additional description: Urge incontinence | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| Endocrine disorders | | | |
| | Additional description: Goitre | | |
| | 1 / 231 (0.43%) | | |
| | 1 | | |
| | Additional description: Hyperthyroidism | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| | Additional description: Hypothyroidism | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| | Additional description: Thyroid cyst | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| | Additional description: Arthropathy | | |
| | 0 / 231 (0.00%) | | |
| | 0 | | |
| | Additional description: Arthritis | | |
| | 7 / 231 (3.03%) | | |
| | 9 | | |
| | Additional description: Arthralgia | | |
| | 44 / 231 (19.05%) | | |
| | 53 | | |
| | Additional description: Back pain | | |
| | 28 / 231 (12.12%) | | |
| | 31 | | |
| | Additional description: Bone pain | | |
| | 5 / 231 (2.16%) | | |
| | 5 | | |
| | Additional description: Bursal haematoma | | |
| | | | |

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|---------------------------------|---|--|--|
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bursitis | Additional description: Bursitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Cervical spinal stenosis | Additional description: Cervical spinal stenosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Exostosis | Additional description: Exostosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fibromyalgia | Additional description: Fibromyalgia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Flank pain | Additional description: Flank pain | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Groin pain | Additional description: Groin pain | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypercreatinaemia | Additional description: Hypercreatinaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Intervertebral disc disorder | Additional description: Intervertebral disc disorder | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Intervertebral disc protrusion | Additional description: Intervertebral disc protrusion | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint effusion | Additional description: Joint effusion | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 3 | | |
| Joint range of motion decreased | Additional description: Joint range of motion decreased | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint swelling | Additional description: Joint swelling | | |

| | | | |
|-----------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 2 | | |
| Limb discomfort | Additional description: Limb discomfort | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Mobility decreased | Additional description: Mobility decreased | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Muscle fatigue | Additional description: Muscle fatigue | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle hypertrophy | Additional description: Muscle hypertrophy | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle spasms | Additional description: Muscle spasms | | |
| subjects affected / exposed | 21 / 231 (9.09%) | | |
| occurrences (all) | 24 | | |
| Muscle tightness | Additional description: Muscle tightness | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Muscle twitching | Additional description: Muscle twitching | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Muscular weakness | Additional description: Muscular weakness | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Musculoskeletal chest pain | Additional description: Musculoskeletal chest pain | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 5 | | |
| Musculoskeletal discomfort | Additional description: Musculoskeletal discomfort | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Musculoskeletal pain | Additional description: Musculoskeletal pain | | |
| subjects affected / exposed | 8 / 231 (3.46%) | | |
| occurrences (all) | 8 | | |
| Musculoskeletal stiffness | Additional description: Musculoskeletal stiffness | | |

| | | | |
|-----------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Myalgia | Additional description: Myalgia | | |
| subjects affected / exposed | 15 / 231 (6.49%) | | |
| occurrences (all) | 16 | | |
| Neck pain | Additional description: Neck pain | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Myositis | Additional description: Myositis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Osteoarthritis | Additional description: Osteoarthritis | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 3 | | |
| Osteonecrosis | Additional description: Osteonecrosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Osteoporosis | Additional description: Osteoporosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Pain in extremity | Additional description: Pain in extremity | | |
| subjects affected / exposed | 7 / 231 (3.03%) | | |
| occurrences (all) | 7 | | |
| Pain in jaw | Additional description: Pain in jaw | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Periarthritis | Additional description: Periarthritis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 2 | | |
| Polyarthritis | Additional description: Polyarthritis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Polymyalgia rheumatica | Additional description: Polymyalgia rheumatica | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psoriatic arthropathy | Additional description: Psoriatic arthropathy | | |

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|------------------------------|--|--|--|
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Rheumatic disorder | Additional description: Rheumatic disorder | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Spinal column stenosis | Additional description: Spinal column stenosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Spinal pain | Additional description: Spinal pain | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 4 | | |
| Tendon disorder | Additional description: Tendon disorder | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tendonitis | Additional description: Tendonitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Vertebral foraminal stenosis | Additional description: Vertebral foraminal stenosis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Infections and infestations | | | |
| Abscess limb | Additional description: Abscess limb | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal infection | Additional description: Abdominal infection | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acarodermatitis | Additional description: Acarodermatitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Abscess | Additional description: Abscess | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 2 | | |
| Acute sinusitis | Additional description: Acute sinusitis | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 2 | | |

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|--|--|--|
| Atypical pneumonia subjects affected / exposed occurrences (all) | Additional description: Atypical pneumonia | |
| | 0 / 231 (0.00%) 0 | |
| Bacterial blepharitis subjects affected / exposed occurrences (all) | Additional description: Bacterial blepharitis | |
| | 0 / 231 (0.00%) 0 | |
| Bacterial food poisoning subjects affected / exposed occurrences (all) | Additional description: Bacterial food poisoning | |
| | 0 / 231 (0.00%) 0 | |
| Bacterial infection subjects affected / exposed occurrences (all) | Additional description: Bacterial infection | |
| | 1 / 231 (0.43%) 1 | |
| Asymptomatic COVID-19 subjects affected / exposed occurrences (all) | Additional description: Asymptomatic COVID-19 | |
| | 0 / 231 (0.00%) 0 | |
| Bacterial prostatitis subjects affected / exposed occurrences (all) | Additional description: Bacterial prostatitis | |
| | 0 / 231 (0.00%) 0 | |
| Bacteriuria subjects affected / exposed occurrences (all) | Additional description: Bacteriuria | |
| | 0 / 231 (0.00%) 0 | |
| Body tinea subjects affected / exposed occurrences (all) | Additional description: Body tinea | |
| | 0 / 231 (0.00%) 0 | |
| Borrelia infection subjects affected / exposed occurrences (all) | Additional description: Borrelia infection | |
| | 0 / 231 (0.00%) 0 | |
| Bronchitis bacterial subjects affected / exposed occurrences (all) | Additional description: Bronchitis bacterial | |
| | 0 / 231 (0.00%) 0 | |
| Bronchopulmonary aspergillosis subjects affected / exposed occurrences (all) | Additional description: Bronchopulmonary aspergillosis | |
| | 0 / 231 (0.00%) 0 | |
| Bursitis infective subjects affected / exposed occurrences (all) | Additional description: Bursitis infective | |
| | 0 / 231 (0.00%) 0 | |

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|---|---|--|
| Campylobacter gastroenteritis subjects affected / exposed occurrences (all) | Additional description: Campylobacter gastroenteritis | |
| | 0 / 231 (0.00%) 0 | |
| Candida infection subjects affected / exposed occurrences (all) | Additional description: Candida infection | |
| | 3 / 231 (1.30%) 3 | |
| Bronchitis subjects affected / exposed occurrences (all) | Additional description: Bronchitis | |
| | 27 / 231 (11.69%) 29 | |
| Cellulitis subjects affected / exposed occurrences (all) | Additional description: Cellulitis | |
| | 3 / 231 (1.30%) 4 | |
| Chronic sinusitis subjects affected / exposed occurrences (all) | Additional description: Chronic sinusitis | |
| | 2 / 231 (0.87%) 3 | |
| Clostridium difficile colitis subjects affected / exposed occurrences (all) | Additional description: Clostridium difficile colitis | |
| | 1 / 231 (0.43%) 1 | |
| Clostridium difficile infection subjects affected / exposed occurrences (all) | Additional description: Clostridium difficile infection | |
| | 0 / 231 (0.00%) 0 | |
| Conjunctivitis subjects affected / exposed occurrences (all) | Additional description: Conjunctivitis | |
| | 17 / 231 (7.36%) 22 | |
| COVID-19 subjects affected / exposed occurrences (all) | Additional description: COVID-19 | |
| | 42 / 231 (18.18%) 48 | |
| COVID-19 pneumonia subjects affected / exposed occurrences (all) | Additional description: COVID-19 pneumonia | |
| | 0 / 231 (0.00%) 0 | |
| Cystitis subjects affected / exposed occurrences (all) | Additional description: Cystitis | |
| | 11 / 231 (4.76%) 22 | |
| Cytomegalovirus infection subjects affected / exposed occurrences (all) | Additional description: Cytomegalovirus infection | |
| | 0 / 231 (0.00%) 0 | |

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| Dacryocanaliculitis | Additional description: Dacryocanaliculitis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Dacryocystitis | Additional description: Dacryocystitis | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Device related infection | Additional description: Device related infection | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Dengue fever | Additional description: Dengue fever | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Diverticulitis | Additional description: Diverticulitis | |
| subjects affected / exposed | 3 / 231 (1.30%) | |
| occurrences (all) | 3 | |
| Ear infection | Additional description: Ear infection | |
| subjects affected / exposed | 6 / 231 (2.60%) | |
| occurrences (all) | 8 | |
| Ear infection bacterial | Additional description: Ear infection bacterial | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Erythema migrans | Additional description: Erythema migrans | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Enterococcal infection | Additional description: Enterococcal infection | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Enterococcal sepsis | Additional description: Enterococcal sepsis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Epididymitis | Additional description: Epididymitis | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Erysipelas | Additional description: Erysipelas | |
| subjects affected / exposed | 5 / 231 (2.16%) | |
| occurrences (all) | 6 | |

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|-----------------------------|--|--|
| Eye infection | Additional description: Eye infection | |
| subjects affected / exposed | 3 / 231 (1.30%) | |
| occurrences (all) | 3 | |
| Eyelid infection | Additional description: Eyelid infection | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Febrile infection | Additional description: Febrile infection | |
| subjects affected / exposed | 5 / 231 (2.16%) | |
| occurrences (all) | 5 | |
| Folliculitis | Additional description: Folliculitis | |
| subjects affected / exposed | 3 / 231 (1.30%) | |
| occurrences (all) | 3 | |
| Fungal infection | Additional description: Fungal infection | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Fungal skin infection | Additional description: Fungal skin infection | |
| subjects affected / exposed | 3 / 231 (1.30%) | |
| occurrences (all) | 3 | |
| Furuncle | Additional description: Furuncle | |
| subjects affected / exposed | 3 / 231 (1.30%) | |
| occurrences (all) | 4 | |
| Genital infection fungal | Additional description: Genital infection fungal | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Genital herpes | Additional description: Genital herpes | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Giardiasis | Additional description: Giardiasis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Gastric infection | Additional description: Gastric infection | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Gastroenteritis | Additional description: Gastroenteritis | |
| subjects affected / exposed | 8 / 231 (3.46%) | |
| occurrences (all) | 8 | |

| | | |
|---|---|--|
| Gastroenteritis caliciviral subjects affected / exposed occurrences (all) | Additional description: Gastroenteritis caliciviral | |
| | 0 / 231 (0.00%) 0 | |
| Gastroenteritis viral subjects affected / exposed occurrences (all) | Additional description: Gastroenteritis viral | |
| | 0 / 231 (0.00%) 0 | |
| Gastrointestinal disorders subjects affected / exposed occurrences (all) | Additional description: Gastrointestinal disorders | |
| | 0 / 231 (0.00%) 0 | |
| Gastrointestinal infection subjects affected / exposed occurrences (all) | Additional description: Gastrointestinal infection | |
| | 2 / 231 (0.87%) 2 | |
| Haemophilus infection subjects affected / exposed occurrences (all) | Additional description: Haemophilus infection | |
| | 1 / 231 (0.43%) 1 | |
| Gingivitis subjects affected / exposed occurrences (all) | Additional description: Gingivitis | |
| | 2 / 231 (0.87%) 3 | |
| Herpes infection subjects affected / exposed occurrences (all) | Additional description: Herpes infection | |
| | 0 / 231 (0.00%) 0 | |
| Helicobacter gastritis subjects affected / exposed occurrences (all) | Additional description: Helicobacter gastritis | |
| | 0 / 231 (0.00%) 0 | |
| Hepatitis B reactivation subjects affected / exposed occurrences (all) | Additional description: Hepatitis B reactivation | |
| | 1 / 231 (0.43%) 1 | |
| Hepatitis E subjects affected / exposed occurrences (all) | Additional description: Hepatitis E | |
| | 0 / 231 (0.00%) 0 | |
| Hepatitis viral subjects affected / exposed occurrences (all) | Additional description: Hepatitis viral | |
| | 0 / 231 (0.00%) 0 | |
| Herpes dermatitis subjects affected / exposed occurrences (all) | Additional description: Herpes dermatitis | |
| | 0 / 231 (0.00%) 0 | |

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|--|--|--|--|
| Herpes simplex subjects affected / exposed occurrences (all) | Additional description: Herpes simplex 5 / 231 (2.16%) 5 | | |
| Herpes simplex reactivation subjects affected / exposed occurrences (all) | Additional description: Herpes simplex reactivation 0 / 231 (0.00%) 0 | | |
| Hordeolum subjects affected / exposed occurrences (all) | Additional description: Hordeolum 2 / 231 (0.87%) 2 | | |
| Herpes zoster subjects affected / exposed occurrences (all) | Additional description: Herpes zoster 8 / 231 (3.46%) 8 | | |
| Herpes virus infection subjects affected / exposed occurrences (all) | Additional description: Herpes virus infection 2 / 231 (0.87%) 2 | | |
| Herpes viral infections subjects affected / exposed occurrences (all) | Additional description: Herpes viral infections 0 / 231 (0.00%) 0 | | |
| Infection subjects affected / exposed occurrences (all) | Additional description: Infection 9 / 231 (3.90%) 10 | | |
| Infection susceptibility increased subjects affected / exposed occurrences (all) | Additional description: Infection susceptibility increased 0 / 231 (0.00%) 0 | | |
| Infectious colitis subjects affected / exposed occurrences (all) | Additional description: Infectious colitis 1 / 231 (0.43%) 1 | | |
| Infective iritis subjects affected / exposed occurrences (all) | Additional description: Infective iritis 1 / 231 (0.43%) 1 | | |
| Impetigo subjects affected / exposed occurrences (all) | Additional description: Impetigo 3 / 231 (1.30%) 3 | | |
| Infected bite subjects affected / exposed occurrences (all) | Additional description: Infected bite 0 / 231 (0.00%) 0 | | |

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|---|---|--|
| Infected dermal cyst subjects affected / exposed occurrences (all) | Additional description: Infected dermal cyst | |
| | 0 / 231 (0.00%) 0 | |
| Infected skin ulcer subjects affected / exposed occurrences (all) | Additional description: Infected skin ulcer | |
| | 1 / 231 (0.43%) 1 | |
| Injection site cellulitis subjects affected / exposed occurrences (all) | Additional description: Injection site cellulitis | |
| | 0 / 231 (0.00%) 0 | |
| Influenza subjects affected / exposed occurrences (all) | Additional description: Influenza | |
| | 7 / 231 (3.03%) 8 | |
| Joint abscess subjects affected / exposed occurrences (all) | Additional description: Joint abscess | |
| | 0 / 231 (0.00%) 0 | |
| Kidney infection subjects affected / exposed occurrences (all) | Additional description: Kidney infection | |
| | 0 / 231 (0.00%) 0 | |
| Labyrinthitis subjects affected / exposed occurrences (all) | Additional description: Labyrinthitis | |
| | 1 / 231 (0.43%) 1 | |
| Laryngitis subjects affected / exposed occurrences (all) | Additional description: Laryngitis | |
| | 3 / 231 (1.30%) 3 | |
| Lip infection subjects affected / exposed occurrences (all) | Additional description: Lip infection | |
| | 1 / 231 (0.43%) 1 | |
| Localised infection subjects affected / exposed occurrences (all) | Additional description: Localised infection | |
| | 1 / 231 (0.43%) 2 | |
| Lower respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Lower respiratory tract infection | |
| | 2 / 231 (0.87%) 5 | |
| Lyme disease subjects affected / exposed occurrences (all) | Additional description: Lyme disease | |
| | 0 / 231 (0.00%) 0 | |

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|---|---|--|
| Lymph gland infection subjects affected / exposed occurrences (all) | Additional description: Lymph gland infection | |
| | 0 / 231 (0.00%) 0 | |
| Metapneumovirus infection subjects affected / exposed occurrences (all) | Additional description: Metapneumovirus infection | |
| | 1 / 231 (0.43%) 1 | |
| Mucosal infection subjects affected / exposed occurrences (all) | Additional description: Mucosal infection | |
| | 2 / 231 (0.87%) 2 | |
| Nail infection subjects affected / exposed occurrences (all) | Additional description: Nail infection | |
| | 3 / 231 (1.30%) 3 | |
| Nasal candidiasis subjects affected / exposed occurrences (all) | Additional description: Nasal candidiasis | |
| | 1 / 231 (0.43%) 1 | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | Additional description: Nasopharyngitis | |
| | 46 / 231 (19.91%) 68 | |
| Onychomycosis subjects affected / exposed occurrences (all) | Additional description: Onychomycosis | |
| | 2 / 231 (0.87%) 2 | |
| Neutropenic infection subjects affected / exposed occurrences (all) | Additional description: Neutropenic infection | |
| | 0 / 231 (0.00%) 0 | |
| Omphalitis subjects affected / exposed occurrences (all) | Additional description: Omphalitis | |
| | 1 / 231 (0.43%) 1 | |
| Ophthalmic herpes zoster subjects affected / exposed occurrences (all) | Additional description: Ophthalmic herpes zoster | |
| | 0 / 231 (0.00%) 0 | |
| Oral candidiasis subjects affected / exposed occurrences (all) | Additional description: Oral candidiasis | |
| | 1 / 231 (0.43%) 1 | |
| Oral fungal infection subjects affected / exposed occurrences (all) | Additional description: Oral fungal infection | |
| | 1 / 231 (0.43%) 1 | |

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|--|--|--|
| Oral herpes subjects affected / exposed occurrences (all) | Additional description: Oral herpes | |
| | 8 / 231 (3.46%) 8 | |
| Oral infection subjects affected / exposed occurrences (all) | Additional description: Oral infection | |
| | 1 / 231 (0.43%) 1 | |
| Oropharyngeal candidiasis subjects affected / exposed occurrences (all) | Additional description: Oropharyngeal candidiasis | |
| | 1 / 231 (0.43%) 1 | |
| Osteomyelitis subjects affected / exposed occurrences (all) | Additional description: Osteomyelitis | |
| | 1 / 231 (0.43%) 1 | |
| Otitis media subjects affected / exposed occurrences (all) | Additional description: Otitis media | |
| | 2 / 231 (0.87%) 2 | |
| Otitis media acute subjects affected / exposed occurrences (all) | Additional description: Otitis media acute | |
| | 1 / 231 (0.43%) 1 | |
| Otitis media chronic subjects affected / exposed occurrences (all) | Additional description: Otitis media chronic | |
| | 0 / 231 (0.00%) 0 | |
| Penile infection subjects affected / exposed occurrences (all) | Additional description: Penile infection | |
| | 0 / 231 (0.00%) 0 | |
| Papilloma viral infection subjects affected / exposed occurrences (all) | Additional description: Papilloma viral infection | |
| | 0 / 231 (0.00%) 0 | |
| Parainfluenzae virus infection subjects affected / exposed occurrences (all) | Additional description: Parainfluenzae virus infection | |
| | 1 / 231 (0.43%) 1 | |
| Paronychia subjects affected / exposed occurrences (all) | Additional description: Paronychia | |
| | 3 / 231 (1.30%) 3 | |
| Parotitis subjects affected / exposed occurrences (all) | Additional description: Parotitis | |
| | 0 / 231 (0.00%) 0 | |

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| Peritonsillar abscess | Additional description: Peritonsillar abscess | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Pharyngitis | Additional description: Pharyngitis | |
| subjects affected / exposed | 4 / 231 (1.73%) | |
| occurrences (all) | 4 | |
| Pharyngitis bacterial | Additional description: Pharyngitis bacterial | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Pharyngotonsillitis | Additional description: Pharyngotonsillitis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Pneumonia mycoplasmal | Additional description: Pneumonia mycoplasmal | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Pneumonia streptococcal | Additional description: Pneumonia streptococcal | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Post-acute COVID-19 syndrome | Additional description: Post-acute COVID-19 syndrome | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Postoperative wound infection | Additional description: Postoperative wound infection | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Pneumonia | Additional description: Pneumonia | |
| subjects affected / exposed | 23 / 231 (9.96%) | |
| occurrences (all) | 30 | |
| Pulpitis dental | Additional description: Pulpitis dental | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Pyelonephritis | Additional description: Pyelonephritis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Pyuria | Additional description: Pyuria | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |

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| Respiratory syncytial virus infection subjects affected / exposed occurrences (all) | Additional description: Respiratory syncytial virus infection | |
| | 0 / 231 (0.00%) 0 | |
| Respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Respiratory tract infection | |
| | 12 / 231 (5.19%) 14 | |
| Respiratory tract infection viral subjects affected / exposed occurrences (all) | Additional description: Respiratory tract infection viral | |
| | 0 / 231 (0.00%) 0 | |
| Rhinitis subjects affected / exposed occurrences (all) | Additional description: Rhinitis | |
| | 8 / 231 (3.46%) 9 | |
| Sialoadenitis subjects affected / exposed occurrences (all) | Additional description: Sialoadenitis | |
| | 2 / 231 (0.87%) 2 | |
| Root canal infection subjects affected / exposed occurrences (all) | Additional description: Root canal infection | |
| | 0 / 231 (0.00%) 0 | |
| Scarlet fever subjects affected / exposed occurrences (all) | Additional description: Scarlet fever | |
| | 1 / 231 (0.43%) 1 | |
| Scrotal infection subjects affected / exposed occurrences (all) | Additional description: Scrotal infection | |
| | 1 / 231 (0.43%) 1 | |
| Sebaceous gland infection subjects affected / exposed occurrences (all) | Additional description: Sebaceous gland infection | |
| | 1 / 231 (0.43%) 1 | |
| Sinusitis subjects affected / exposed occurrences (all) | Additional description: Sinusitis | |
| | 18 / 231 (7.79%) 21 | |
| Skin infection subjects affected / exposed occurrences (all) | Additional description: Skin infection | |
| | 5 / 231 (2.16%) 7 | |
| Soft tissue infection subjects affected / exposed occurrences (all) | Additional description: Soft tissue infection | |
| | 1 / 231 (0.43%) 1 | |

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|-----------------------------|--|--|
| Staphylococcal infection | Additional description: Staphylococcal infection | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Subcutaneous abscess | Additional description: Subcutaneous abscess | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Sycosis barbae | Additional description: Sycosis barbae | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Tinea pedis | Additional description: Tinea pedis | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 3 | |
| Tinea infection | Additional description: Tinea infection | |
| subjects affected / exposed | 2 / 231 (0.87%) | |
| occurrences (all) | 2 | |
| Tonsillitis | Additional description: Tonsillitis | |
| subjects affected / exposed | 6 / 231 (2.60%) | |
| occurrences (all) | 6 | |
| Tooth abscess | Additional description: Tooth abscess | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Tooth infection | Additional description: Tooth infection | |
| subjects affected / exposed | 4 / 231 (1.73%) | |
| occurrences (all) | 4 | |
| Tracheitis | Additional description: Tracheitis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |
| Urethritis | Additional description: Urethritis | |
| subjects affected / exposed | 1 / 231 (0.43%) | |
| occurrences (all) | 1 | |
| Vaginal infection | Additional description: Vaginal infection | |
| subjects affected / exposed | 6 / 231 (2.60%) | |
| occurrences (all) | 6 | |
| Urosepsis | Additional description: Urosepsis | |
| subjects affected / exposed | 0 / 231 (0.00%) | |
| occurrences (all) | 0 | |

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| Urinary tract infection viral subjects affected / exposed occurrences (all) | Additional description: Urinary tract infection viral | |
| | 0 / 231 (0.00%) 0 | |
| Urinary tract infection bacterial subjects affected / exposed occurrences (all) | Additional description: Urinary tract infection bacterial | |
| | 1 / 231 (0.43%) 2 | |
| Urinary tract infection subjects affected / exposed occurrences (all) | Additional description: Urinary tract infection | |
| | 29 / 231 (12.55%) 47 | |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Upper respiratory tract infection | |
| | 37 / 231 (16.02%) 55 | |
| Viral upper respiratory tract infection subjects affected / exposed occurrences (all) | Additional description: Viral upper respiratory tract infection | |
| | 0 / 231 (0.00%) 0 | |
| Viral sinusitis subjects affected / exposed occurrences (all) | Additional description: Viral sinusitis | |
| | 0 / 231 (0.00%) 0 | |
| Viral infection subjects affected / exposed occurrences (all) | Additional description: Viral infection | |
| | 4 / 231 (1.73%) 5 | |
| Vestibular neuronitis subjects affected / exposed occurrences (all) | Additional description: Vestibular neuronitis | |
| | 0 / 231 (0.00%) 0 | |
| Varicella zoster virus infection subjects affected / exposed occurrences (all) | Additional description: Varicella zoster virus infection | |
| | 0 / 231 (0.00%) 0 | |
| Vulvovaginal candidiasis subjects affected / exposed occurrences (all) | Additional description: Vulvovaginal candidiasis | |
| | 0 / 231 (0.00%) 0 | |
| Vulvovaginal mycotic infection subjects affected / exposed occurrences (all) | Additional description: Vulvovaginal mycotic infection | |
| | 1 / 231 (0.43%) 1 | |
| Wound infection subjects affected / exposed occurrences (all) | Additional description: Wound infection | |
| | 0 / 231 (0.00%) 0 | |

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|------------------------------------|--|--|--|
| Metabolism and nutrition disorders | | | |
| Abnormal weight gain | Additional description: Abnormal weight gain | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Acidosis | Additional description: Acidosis | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Alcohol intolerance | Additional description: Alcohol intolerance | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Decreased appetite | Additional description: Decreased appetite | | |
| subjects affected / exposed | 16 / 231 (6.93%) | | |
| occurrences (all) | 19 | | |
| Diabetes mellitus | Additional description: Diabetes mellitus | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Dehydration | Additional description: Dehydration | | |
| subjects affected / exposed | 2 / 231 (0.87%) | | |
| occurrences (all) | 2 | | |
| Dyslipidaemia | Additional description: Dyslipidaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Fluid overload | Additional description: Fluid overload | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Folate deficiency | Additional description: Folate deficiency | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Gout | Additional description: Gout | | |
| subjects affected / exposed | 3 / 231 (1.30%) | | |
| occurrences (all) | 4 | | |
| Hyperphosphataemia | Additional description: Hyperphosphataemia | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 6 | | |
| Hyperkalaemia | Additional description: Hyperkalaemia | | |

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|-----------------------------|---|--|--|
| subjects affected / exposed | 10 / 231 (4.33%) | | |
| occurrences (all) | 11 | | |
| Hyperglycaemia | Additional description: Hyperglycaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Hypercholesterolaemia | Additional description: Hypercholesterolaemia | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypercalcaemia | Additional description: Hypercalcaemia | | |
| subjects affected / exposed | 4 / 231 (1.73%) | | |
| occurrences (all) | 5 | | |
| Hyponatraemia | Additional description: Hyponatraemia | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 6 | | |
| Hypomagnesaemia | Additional description: Hypomagnesaemia | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 6 | | |
| Hypokalaemia | Additional description: Hypokalaemia | | |
| subjects affected / exposed | 14 / 231 (6.06%) | | |
| occurrences (all) | 20 | | |
| Hypoferritinaemia | Additional description: Hypoferritinaemia | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Hypocalcaemia | Additional description: Hypocalcaemia | | |
| subjects affected / exposed | 6 / 231 (2.60%) | | |
| occurrences (all) | 8 | | |
| Hyperuricaemia | Additional description: Hyperuricaemia | | |
| subjects affected / exposed | 9 / 231 (3.90%) | | |
| occurrences (all) | 10 | | |
| Hypophosphataemia | Additional description: Hypophosphataemia | | |
| subjects affected / exposed | 9 / 231 (3.90%) | | |
| occurrences (all) | 15 | | |
| Increased appetite | Additional description: Increased appetite | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Iron deficiency | Additional description: Iron deficiency | | |

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|-----------------------------|--|--|--|
| subjects affected / exposed | 9 / 231 (3.90%) | | |
| occurrences (all) | 9 | | |
| Iron overload | Additional description: Iron overload | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Obesity | Additional description: Obesity | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |
| Tumour lysis syndrome | Additional description: Tumour lysis syndrome | | |
| subjects affected / exposed | 13 / 231 (5.63%) | | |
| occurrences (all) | 13 | | |
| Type 2 diabetes mellitus | Additional description: Type 2 diabetes mellitus | | |
| subjects affected / exposed | 0 / 231 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin D deficiency | Additional description: Vitamin D deficiency | | |
| subjects affected / exposed | 5 / 231 (2.16%) | | |
| occurrences (all) | 5 | | |
| Vitamin B12 deficiency | Additional description: Vitamin B12 deficiency | | |
| subjects affected / exposed | 1 / 231 (0.43%) | | |
| occurrences (all) | 1 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 20 February 2017 | Israel and Ireland were included as participating countries. Availability of SmPC as reference document for Venetoclax due to approval by EMA in December 2016, additionally, new data for administration of venetoclax became available. The study duration was adapted after start of recruitment. The recommended prophylaxis in case of HBV DNA detection was adapted following the newest guidelines. Due to new safety information for obinutuzumab regarding infections, dose and schedule modifications in the RVe/GVe or GIVe arm were adapted. New safety information for ibrutinib regarding interstitial lung disease became available and was included in the protocol. Ultrasound testing at baseline was deleted from the protocol, as CT/MRI is mandatory at baseline. |
| 13 July 2017 | The non-use of Rituximab bio-similars was specified in the protocol. MRD measurements are no longer performed by four-color, but by multi-colour-flow-cytometry. Dose and schedule modifications for venetoclax in case of febrile neutropenia and thrombocytopenia during ramp up were clarified. An additional appendix for TLS-risk-management was added. |
| 05 September 2017 | Amendment following updated Venetoclax IMPD. Changes in PIC due to EU general data protection regulation were made, not all countries were affected. |
| 12 December 2018 | Cancer Trials Ireland and the Israeli CLL Study Group were added as participating study group in the title. Additional participating protocol committee members were added as well as the coordinating physician. Accepted delay of study visits was extended to +/- 14 days. Prior treatment with rituximab was added as an exclusion criterion. Hospitalization as prophylaxis of TLS in venetoclax as well as the 2h-post-venetoclax laboratory assessment were not necessarily recommended anymore. Non TLS-related hyperphosphatemia is not a reason for interruption of venetoclax treatment anymore. Due to possibly increased rate of aspergilloses in ibrutinib-containing treatment, recommendations concerning infection prophylaxis were added to the protocol. Adjustments according to SmPC of venetoclax were made. |
| 19 February 2020 | Changes on frequency of HBV PCR testing were made, pelvis and was included in radiological assessment at baseline, additional sampling (ctDNA) from pB was added in the protocol. Adjustments in safety reporting were made. |
| 26 April 2021 | Adjustments and specifications of the statistical chapter were made, MRD analysis by MGS was added as an exploratory endpoint. A chapter regarding Benefit-Risk-Assessment during the Covid-19 pandemic was added to the protocol. |
| 26 April 2021 | non-substantial amendment. New SmPCs available |
| 12 December 2022 | FU intervals were updated and extended to 13 months. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/37172204>

<http://www.ncbi.nlm.nih.gov/pubmed/32601378>

<http://www.ncbi.nlm.nih.gov/pubmed/37163621>

<http://www.ncbi.nlm.nih.gov/pubmed/38821083>