# Clinical trial results:
# A Phase 1/2, Open-label, Multi-center Study to Assess the Safety and Tolerability of Durvalumab (Anti-PD-L1 Antibody) as Monotherapy and in Combination Therapy in Subjects With Lymphoma or Chronic Lymphocitic Leukemia

## Summary

| | |
|---|---|
| EudraCT number | 2015-003516-21 |
| Trial protocol | GB DE NL IT |
| Global end of trial date | 21 August 2022 |

### Results information

| | |
|---|---|
| Result version number | v2 (current) |
| This version publication date | 25 October 2023 |
| First version publication date | 06 September 2023 |
| Version creation reason | |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | MEDI4736-NHL-001 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02733042 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Bristol-Myers Squibb |
| Sponsor organisation address | Chaussée de la Hulpe 185, Brussels, Belgium, 1170 |
| Public contact | EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com |
| Scientific contact | Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com |

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 20 August 2022 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 21 August 2022 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To assess the safety and tolerability of durvalumab when given in combination with lenalidomide and rituximab; ibrutinib; or bendamustine and rituximab in participants with lymphoma or chronic lymphocytic leukemia.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 11 May 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 | France: 22 |
| Country: Number of subjects enrolled | Italy: 23 |
| Country: Number of subjects enrolled | Japan: 12 |
| Country: Number of subjects enrolled | United Kingdom: 18 |
| Country: Number of subjects enrolled | United States: 25 |
| Country: Number of subjects enrolled | Netherlands: 6 |
| Worldwide total number of subjects | 106 |
| EEA total number of subjects | 51 |

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) | 44 |
| From 65 to 84 years | 62 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

106 participants were treated.

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Part 1 Arm A: DUR 1500 + LEN 20 |

Arm description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Lenalidomide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| | |
|---|---|
| **Arm title** | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 |

Arm description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5

| | |
|---|---|
| Investigational medicinal product name | Lenalidomide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

| | |
|---|---|
| **Arm title** | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 |

Arm description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m² IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5

| | |
|---|---|
| Investigational medicinal product name | Lenalidomide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13

| | |
|---|---|
| **Arm title** | Part 1 Arm B: DUR 1500 + IBR 420 |

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Arm type | Experimental |

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Ibrutinib (IBR) 420 mg orally once daily

| | |
|---|---|
| **Arm title** | Part 1 Arm B: DUR 1500 + IBR 560 |

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Ibrutinib |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Ibrutinib (IBR) 560 mg orally once daily

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| | |
|---|---|
| **Arm title** | Part 1 Arm C: DUR 1500 + RIT 375 |

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 1 Arm C: DUR 1500 + BEN 70 |
|---|---|

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | Bendamustine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravesical use |

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|

Arm description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| Investigational medicinal product name | Bendamustine |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravesical use |

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the

rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| **Arm title** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|
| Arm description: | |
| Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose). | |
| Arm type | Experimental |
| Investigational medicinal product name | Durvalumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 | |
| Investigational medicinal product name | Bendamustine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravesical use |
| Dosage and administration details: | |
| Bendamustine (BEN) 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6. | |
| Investigational medicinal product name | Rituximab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose). | |
| **Arm title** | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 |
| Arm description: | |
| Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason. | |
| Arm type | Experimental |
| Investigational medicinal product name | Ibrutinib |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |
| Dosage and administration details: | |
| Ibrutinib (IBR) 420 mg orally once daily | |
| Investigational medicinal product name | Durvalumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 2 Arm B MCL: DUR 1500 + IBR 560 |
|---|---|

Arm description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Ibrutinib |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

Ibrutinib (IBR) 560 mg orally once daily

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Arm description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| | |
|---|---|
| Investigational medicinal product name | Bendamustine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravesical use |

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6

| **Arm title** | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Arm description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| Investigational medicinal product name | Bendamustine |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravesical use |

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6

| **Arm title** | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 |
|---|---|

Arm description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

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

Dosage and administration details:

Rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Investigational medicinal product name | Bendamustine |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |

| | |
|---|---|
| Routes of administration | Intravesical use |

Dosage and administration details:

Bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

| **Arm title** | Part 2 Arm D FL: DUR 1500 |
|---|---|

Arm description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|

Arm description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 2 Arm D CLL/SLL: DUR 1500 |
|---|---|

Arm description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 2 Arm D MCL: DUR 1500 |
|---|---|

Arm description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Arm title** | Part 2 Arm D HL: DUR 1500 |
|---|---|

Arm description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

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

Dosage and administration details:

Durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13

| **Number of subjects in period 1** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 |
|---|---|---|---|
| Started | 3 | 3 | 8 |
| Entered follow-up | 3 | 3 | 6 |
| Completed | 0 | 1 | 1 |
| Not completed | 3 | 2 | 7 |
| Adverse event, serious fatal | - | - | - |
| Consent withdrawn by subject | - | 1 | 2 |
| Adverse event, non-fatal | 1 | - | 1 |
| Other Reasons | - | - | 1 |
| Progressive Disease | 2 | 1 | 3 |

| **Number of subjects in period 1** | Part 1 Arm B: DUR 1500 + IBR 420 | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 |
|---|---|---|---|
| Started | 3 | 4 | 3 |
| Entered follow-up | 3 | 2 | 2 |
| Completed | 0 | 1 | 0 |
| Not completed | 3 | 3 | 3 |
| Adverse event, serious fatal | - | - | - |
| Consent withdrawn by subject | 1 | 1 | - |
| Adverse event, non-fatal | 1 | - | - |
| Other Reasons | - | - | - |
| Progressive Disease | 1 | 2 | 3 |

| **Number of subjects in period 1** | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Started | 1 | 4 | 5 |
| Entered follow-up | 0 | 4 | 4 |
| Completed | 0 | 1 | 0 |
| Not completed | 1 | 3 | 5 |
| Adverse event, serious fatal | 1 | - | 1 |
| Consent withdrawn by subject | - | - | 1 |
| Adverse event, non-fatal | - | - | - |
| Other Reasons | - | - | - |
| Progressive Disease | - | 3 | 3 |

| **Number of subjects in period 1** | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|
| Started | 10 | 10 | 10 |
| Entered follow-up | 4 [1] | 5 | 9 |
| Completed | 6 | 4 | 4 |
| Not completed | 4 | 6 | 6 |
| Adverse event, serious fatal | - | 1 | - |
| Consent withdrawn by subject | 1 | - | 2 |
| Adverse event, non-fatal | - | 2 | 2 |
| Other Reasons | 1 | 1 | - |
| Progressive Disease | 2 | 2 | 2 |

| **Number of subjects in period 1** | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 |
|---|---|---|---|
| Started | 10 | 5 | 5 |
| Entered follow-up | 9 | 4 | 1 |
| Completed | 1 | 1 | 0 |
| Not completed | 9 | 4 | 5 |
| Adverse event, serious fatal | - | - | 1 |
| Consent withdrawn by subject | 1 | 1 | - |
| Adverse event, non-fatal | - | 2 | - |
| Other Reasons | - | - | - |
| Progressive Disease | 8 | 1 | 4 |

| **Number of subjects in period 1** | Part 2 Arm D DLBCL: DUR 1500 | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 |
|---|---|---|---|
| Started | 10 | 2 | 5 |
| Entered follow-up | 5 | 0 | 3 |
| Completed | 0 | 0 | 0 |
| Not completed | 10 | 2 | 5 |
| Adverse event, serious fatal | 2 | - | - |
| Consent withdrawn by subject | - | - | - |
| Adverse event, non-fatal | - | - | 1 |
| Other Reasons | 1 | - | 1 |

| | | | |
|---|---|---|---|
| Progressive Disease | 7 | 2 | 3 |

| **Number of subjects in period 1** | Part 2 Arm D HL: DUR 1500 |
|---|---|
| Started | 5 |
| Entered follow-up | 2 |
| Completed | 1 |
| Not completed | 4 |
| Adverse event, serious fatal | - |
| Consent withdrawn by subject | - |
| Adverse event, non-fatal | - |
| Other Reasons | - |
| Progressive Disease | 4 |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 106 participants were treated. 69 participants entered follow-up period after completing or discontinuing study treatment.

## Reporting groups

| Reporting group title | Part 1 Arm A: DUR 1500 + LEN 20 |
|---|---|

Reporting group description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

| Reporting group title | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 |
|---|---|

Reporting group description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

| Reporting group title | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 |
|---|---|

Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m² IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

| Reporting group title | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 1 Arm B: DUR 1500 + IBR 560 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 1 Arm C: DUR 1500 + RIT 375 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 1 Arm C: DUR 1500 + BEN 70 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

| Reporting group title | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 |
|---|---|

Reporting group description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received

durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 2 Arm B MCL: DUR 1500 + IBR 560 |
|---|---|

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| Reporting group title | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| Reporting group title | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 |
|---|---|

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 2 Arm D FL: DUR 1500 |
|---|---|

Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D CLL/SLL: DUR 1500 |
|---|---|

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D MCL: DUR 1500 |
|---|---|

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D HL: DUR 1500 |
|---|---|

Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| **Reporting group values** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 |
|---|---|---|---|
| Number of subjects | 3 | 3 | 8 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 1 | 1 | 2 |
| ≥ 65 Years | 2 | 2 | 6 |
| Age Continuous<br>Units: years | | | |
| median | 71.0 | 66.0 | 77.0 |
| full range (min-max) | 50 to 78 | 52 to 75 | 53 to 80 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 1 | 0 | 2 |
| Male | 2 | 3 | 6 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 2 | 2 | 7 |
| Unknown or Not Reported | 1 | 1 | 1 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 2 | 2 | 3 |
| Asian | 0 | 0 | 3 |
| Black or African American | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 0 | 0 | 1 |
| Not Collected or Reported | 1 | 1 | 1 |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 1 | 3 | 1 |
| Diffuse large B-cell lymphoma | 2 | 0 | 4 |
| Marginal zone lymphoma | 0 | 0 | 2 |
| Transformed follicular lymphoma | 0 | 0 | 1 |
| Mantle cell lymphoma | 0 | 0 | 0 |
| CLL / SLL | 0 | 0 | 0 |
| Hodgkin lymphoma | 0 | 0 | 0 |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 0 | 2 | 2 |
| 1 - Restricted but ambulatory | 3 | 1 | 4 |
| 2 - Ambulatory but unable to work | 0 | 0 | 2 |
| 3 - Limited self-care | 0 | 0 | 0 |

| **Reporting group values** | Part 1 Arm B: DUR 1500 + IBR 420 | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 |
|---|---|---|---|
| Number of subjects | 3 | 4 | 3 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 2 | 1 | 0 |
| ≥ 65 Years | 1 | 3 | 3 |
| Age Continuous<br>Units: years | | | |
| median | 58.0 | 68.0 | 79.0 |
| full range (min-max) | 54 to 74 | 57 to 81 | 76 to 80 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 0 | 2 | 2 |
| Male | 3 | 2 | 1 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 1 | 0 |
| Not Hispanic or Latino | 2 | 3 | 1 |
| Unknown or Not Reported | 1 | 0 | 2 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 2 | 4 | 0 |
| Asian | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Not Collected or Reported | 1 | 0 | 3 |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 1 | 0 | 1 |
| Diffuse large B-cell lymphoma | 0 | 0 | 2 |
| Marginal zone lymphoma | 0 | 3 | 0 |
| Transformed follicular lymphoma | 0 | 0 | 0 |
| Mantle cell lymphoma | 1 | 1 | 0 |
| CLL / SLL | 1 | 0 | 0 |
| Hodgkin lymphoma | 0 | 0 | 0 |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 0 | 1 | 1 |
| 1 - Restricted but ambulatory | 3 | 3 | 2 |
| 2 - Ambulatory but unable to work | 0 | 0 | 0 |
| 3 - Limited self-care | 0 | 0 | 0 |

| **Reporting group values** | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|---|---|
| Number of subjects | 1 | 4 | 5 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 0 | 1 | 3 |
| ≥ 65 Years | 1 | 3 | 2 |
| Age Continuous<br>Units: years | | | |
| median | 70.0 | 68.0 | 38.0 |
| full range (min-max) | 70 to 70 | 52 to 78 | 21 to 77 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 0 | 1 | 3 |
| Male | 1 | 3 | 2 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 1 | 3 | 3 |
| Unknown or Not Reported | 0 | 1 | 2 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 1 | 0 | 4 |
| Asian | 0 | 3 | 1 |
| Black or African American | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Not Collected or Reported | 0 | 1 | 0 |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 0 | 1 | 0 |
| Diffuse large B-cell lymphoma | 1 | 3 | 5 |
| Marginal zone lymphoma | 0 | 0 | 0 |
| Transformed follicular lymphoma | 0 | 0 | 0 |
| Mantle cell lymphoma | 0 | 0 | 0 |
| CLL / SLL | 0 | 0 | 0 |
| Hodgkin lymphoma | 0 | 0 | 0 |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 0 | 3 | 2 |
| 1 - Restricted but ambulatory | 0 | 0 | 2 |
| 2 - Ambulatory but unable to work | 1 | 1 | 1 |
| 3 - Limited self-care | 0 | 0 | 0 |

| **Reporting group values** | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|
| Number of subjects | 10 | 10 | 10 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 4 | 2 | 5 |
| ≥ 65 Years | 6 | 8 | 5 |
| Age Continuous<br>Units: years | | | |
| median | 68.0 | 73.5 | 64.5 |
| full range (min-max) | 55 to 73 | 54 to 84 | 45 to 75 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 3 | 1 | 3 |
| Male | 7 | 9 | 7 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 5 | 7 | 6 |
| Unknown or Not Reported | 5 | 3 | 4 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 5 | 6 | 4 |
| Asian | 0 | 1 | 1 |
| Black or African American | 0 | 0 | 1 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Not Collected or Reported | 5 | 3 | 4 |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 0 | 0 | 10 |
| Diffuse large B-cell lymphoma | 0 | 0 | 0 |
| Marginal zone lymphoma | 0 | 0 | 0 |
| Transformed follicular lymphoma | 0 | 0 | 0 |
| Mantle cell lymphoma | 0 | 10 | 0 |
| CLL / SLL | 10 | 0 | 0 |
| Hodgkin lymphoma | 0 | 0 | 0 |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 8 | 6 | 6 |
| 1 - Restricted but ambulatory | 2 | 3 | 3 |
| 2 - Ambulatory but unable to work | 0 | 1 | 1 |
| 3 - Limited self-care | 0 | 0 | 0 |

| **Reporting group values** | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 |
|---|---|---|---|
| Number of subjects | 10 | 5 | 5 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 7 | 2 | 3 |
| ≥ 65 Years | 3 | 3 | 2 |
| Age Continuous<br>Units: years | | | |
| median | 60.0 | 68.0 | 52.0 |
| full range (min-max) | 46 to 71 | 53 to 79 | 39 to 71 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 4 | 2 | 2 |
| Male | 6 | 3 | 3 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 1 | 0 |
| Not Hispanic or Latino | 8 | 3 | 2 |
| Unknown or Not Reported | 2 | 1 | 3 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 4 | 4 | 2 |
| Asian | 3 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 1 | 0 | 0 |
| Not Collected or Reported | 2 | 1 | 3 |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 0 | 0 | 5 |
| Diffuse large B-cell lymphoma | 10 | 0 | 0 |
| Marginal zone lymphoma | 0 | 0 | 0 |
| Transformed follicular lymphoma | 0 | 0 | 0 |
| Mantle cell lymphoma | 0 | 0 | 0 |
| CLL / SLL | 0 | 5 | 0 |
| Hodgkin lymphoma | 0 | 0 | 0 |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 7 | 0 | 2 |
| 1 - Restricted but ambulatory | 1 | 4 | 2 |
| 2 - Ambulatory but unable to work | 2 | 1 | 1 |
| 3 - Limited self-care | 0 | 0 | 0 |

| **Reporting group values** | Part 2 Arm D DLBCL: DUR 1500 | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 |
|---|---|---|---|
| Number of subjects | 10 | 2 | 5 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 5 | 1 | 0 |
| ≥ 65 Years | 5 | 1 | 5 |
| Age Continuous<br>Units: years | | | |
| median | 61.5 | 62.0 | 77.0 |
| full range (min-max) | 22 to 76 | 55 to 69 | 69 to 80 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 4 | 1 | 2 |
| Male | 6 | 1 | 3 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 9 | 2 | 5 |
| Unknown or Not Reported | 1 | 0 | 0 |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 9 | 2 | 4 |
| Asian | 0 | 0 | 1 |
| Black or African American | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Not Collected or Reported | 1 | 0 | 0 |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 0 | 0 | 0 |
| Diffuse large B-cell lymphoma | 10 | 0 | 0 |
| Marginal zone lymphoma | 0 | 0 | 0 |
| Transformed follicular lymphoma | 0 | 0 | 0 |
| Mantle cell lymphoma | 0 | 0 | 5 |
| CLL / SLL | 0 | 2 | 0 |
| Hodgkin lymphoma | 0 | 0 | 0 |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 3 | 1 | 4 |
| 1 - Restricted but ambulatory | 4 | 1 | 1 |
| 2 - Ambulatory but unable to work | 2 | 0 | 0 |
| 3 - Limited self-care | 1 | 0 | 0 |

| **Reporting group values** | Part 2 Arm D HL: DUR 1500 | Total | |
|---|---|---|---|
| Number of subjects | 5 | 106 | |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 4 | 44 | |
| ≥ 65 Years | 1 | 62 | |
| Age Continuous<br>Units: years | | | |
| median | 51.0 | | |
| full range (min-max) | 34 to 65 | - | |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: participants | | | |
| Female | 2 | 35 | |
| Male | 3 | 71 | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 2 | |
| Not Hispanic or Latino | 5 | 76 | |
| Unknown or Not Reported | 0 | 28 | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 5 | 63 | |
| Asian | 0 | 13 | |
| Black or African American | 0 | 1 | |
| American Indian or Alaska Native | 0 | 0 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Other | 0 | 2 | |
| Not Collected or Reported | 0 | 27 | |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 0 | 23 | |
| Diffuse large B-cell lymphoma | 0 | 37 | |
| Marginal zone lymphoma | 0 | 5 | |
| Transformed follicular lymphoma | 0 | 1 | |
| Mantle cell lymphoma | 0 | 17 | |
| CLL / SLL | 0 | 18 | |
| Hodgkin lymphoma | 5 | 5 | |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 5 | 53 | |
| 1 - Restricted but ambulatory | 0 | 39 | |
| 2 - Ambulatory but unable to work | 0 | 13 | |
| 3 - Limited self-care | 0 | 1 | |

**Subject analysis sets**

| | |
|---|---|
| Subject analysis set title | Part 1, Arm C: DUR 1500 mg + RIT 375 mg/mÂ² + BEN 90 mg/m² |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description:<br>Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose). | |
| Subject analysis set title | Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG |
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Subject analysis set title | Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m² |
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| | |
|---|---|
| Subject analysis set title | Arm A: Durvalumab + Lenalidomide ± Rituximab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm B: Durvalumab + Ibrutinib |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm B received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 420 or 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Subject analysis set title | Arm C: Durvalumab + Bendamustine ± Rituximab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm C received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, 70 or 90 mg/m² bendamustine IV on Days 1 and 2 of Cycles 1 to 6, and rituximab 375 mg/m² IV on Day 2 of Cycles 1 to 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| | |
|---|---|
| Subject analysis set title | Arm D: Durvalumab Monotherapy |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

| | |
|---|---|
| Subject analysis set title | Arm D: Durvalumab Monotherapy |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

| | |
|---|---|
| Subject analysis set title | Arm A: Durvalumab + Lenalidomide Â± Rituximab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm A: Lenalidomide 10 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants in Arm A received lenalidomide 10 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm A: Lenalidomide 20 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants in Arm A received lenalidomide 20 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for

any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm B: Ibrutinib 420 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm B received 420 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

| | |
|---|---|
| Subject analysis set title | Arm B: Ibrutinib 560 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm B received 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

| **Reporting group values** | Part 1, Arm C: DUR 1500 mg + RIT 375 mg/mÂ² + BEN 90 mg/m² | Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG | Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m² |
|---|---|---|---|
| Number of subjects | 5 | 10 | 10 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | 3 | 4 | |
| ≥ 65 Years | 2 | 6 | |
| Age Continuous<br>Units: years | | | |
| median | 38.0 | 68.0 | 30.0 |
| full range (min-max) | 21 to 77 | 55 to 73 | 6.7 to 65.2 |
| Sex: Female, Male<br>Units: participants | | | |
| Female | 3 | 3 | |
| Male | 2 | 7 | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | |
| Not Hispanic or Latino | 3 | 5 | |
| Unknown or Not Reported | 2 | 5 | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 4 | 5 | |
| Asian | 1 | 0 | |
| Black or African American | 0 | 0 | |
| American Indian or Alaska Native | 0 | 0 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Other | 0 | 0 | |
| Not Collected or Reported | 0 | 5 | |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | 0 | 0 | |
| Diffuse large B-cell lymphoma | 5 | 0 | |
| Marginal zone lymphoma | 0 | 0 | |
| Transformed follicular lymphoma | 0 | 0 | |
| Mantle cell lymphoma | 0 | 0 | |

| | | | |
|---|---|---|---|
| CLL / SLL | 0 | 10 | |
| Hodgkin lymphoma | 0 | 0 | |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active | 2 | 8 | |
| 1 - Restricted but ambulatory | 2 | 2 | |
| 2 - Ambulatory but unable to work | 1 | 0 | |
| 3 - Limited self-care | 0 | 0 | |

| **Reporting group values** | Arm A: Durvalumab + Lenalidomide ± Rituximab | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab |
|---|---|---|---|
| Number of subjects | 14 | 27 | 38 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years | | | |
| ≥ 65 Years | | | |
| Age Continuous<br>Units: years | | | |
| median | | | |
| full range (min-max) | | | |
| Sex: Female, Male<br>Units: participants | | | |
| Female | | | |
| Male | | | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | | | |
| Not Hispanic or Latino | | | |
| Unknown or Not Reported | | | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | | | |
| Asian | | | |
| Black or African American | | | |
| American Indian or Alaska Native | | | |
| Native Hawaiian or Other Pacific Islander | | | |
| Other | | | |
| Not Collected or Reported | | | |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma | | | |
| Diffuse large B-cell lymphoma | | | |
| Marginal zone lymphoma | | | |
| Transformed follicular lymphoma | | | |
| Mantle cell lymphoma | | | |

| | | | |
|---|---|---|---|
| CLL / SLL<br>Hodgkin lymphoma | | | |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient’s level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active<br>1 - Restricted but ambulatory<br>2 - Ambulatory but unable to work<br>3 - Limited self-care | | | |

| **Reporting group values** | Arm D: Durvalumab Monotherapy | Arm D: Durvalumab Monotherapy | Arm A: Durvalumab + Lenalidomide Â± Rituximab |
|---|---|---|---|
| Number of subjects | 26 | 25 | 14 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years<br>≥ 65 Years | | | |
| Age Continuous<br>Units: years<br>median<br>full range (min-max) | | | |
| Sex: Female, Male<br>Units: participants | | | |
| Female<br>Male | | | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino<br>Not Hispanic or Latino<br>Unknown or Not Reported | | | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White<br>Asian<br>Black or African American<br>American Indian or Alaska Native<br>Native Hawaiian or Other Pacific Islander<br>Other<br>Not Collected or Reported | | | |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma<br>Diffuse large B-cell lymphoma<br>Marginal zone lymphoma<br>Transformed follicular lymphoma<br>Mantle cell lymphoma | | | |

| | | | |
|---|---|---|---|
| CLL / SLL<br>Hodgkin lymphoma | | | |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active<br>1 - Restricted but ambulatory<br>2 - Ambulatory but unable to work<br>3 - Limited self-care | | | |

| **Reporting group values** | Arm A: Lenalidomide 10 mg | Arm A: Lenalidomide 20 mg | Arm B: Ibrutinib 420 mg |
|---|---|---|---|
| Number of subjects | 5 | 4 | 13 |
| Age Categorical<br>Units: participants | | | |
| < 65 Years<br>≥ 65 Years | | | |
| Age Continuous<br>Units: years<br>median<br>full range (min-max) | | | |
| Sex: Female, Male<br>Units: participants | | | |
| Female<br>Male | | | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino<br>Not Hispanic or Latino<br>Unknown or Not Reported | | | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White<br>Asian<br>Black or African American<br>American Indian or Alaska Native<br>Native Hawaiian or Other Pacific Islander<br>Other<br>Not Collected or Reported | | | |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma<br>Diffuse large B-cell lymphoma<br>Marginal zone lymphoma<br>Transformed follicular lymphoma<br>Mantle cell lymphoma<br>CLL / SLL | | | |

| | | | |
|---|---|---|---|
| Hodgkin lymphoma | | | |
| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
| ECOG performance status is used to describe a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active<br>1 - Restricted but ambulatory<br>2 - Ambulatory but unable to work<br>3 - Limited self-care | | | |

| **Reporting group values** | Arm B: Ibrutinib 560 mg | | |
|---|---|---|---|
| Number of subjects | 13 | | |
| Age Categorical<br>Units: participants | | | |
| < 65 Years<br>≥ 65 Years | | | |
| Age Continuous<br>Units: years<br>median<br>full range (min-max) | | | |
| Sex: Female, Male<br>Units: participants | | | |
| Female<br>Male | | | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino<br>Not Hispanic or Latino<br>Unknown or Not Reported | | | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White<br>Asian<br>Black or African American<br>American Indian or Alaska Native<br>Native Hawaiian or Other Pacific Islander<br>Other<br>Not Collected or Reported | | | |
| Histology<br>Units: Subjects | | | |
| Follicular lymphoma<br>Diffuse large B-cell lymphoma<br>Marginal zone lymphoma<br>Transformed follicular lymphoma<br>Mantle cell lymphoma<br>CLL / SLL<br>Hodgkin lymphoma | | | |

| Eastern Cooperative Oncology Group ECOG) Performance Status | | | |
|---|---|---|---|
| ECOG performance status is used to describe a patient’s level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). The scale ranges from 0 to 5: • 0 = Fully active, no restrictions; • 1 = Restricted activity but ambulatory, able to carry out work of a light nature; • 2 = Ambulatory and capable of all self-care but unable to carry out work activities; • 3 = Limited self-care, confined to bed or chair more than 50% of waking hours; • 4 = Completely disabled, no selfcare, confined to bed or chair; • 5 = Dead | | | |
| Units: Subjects | | | |
| 0 - Fully Active<br>1 - Restricted but ambulatory<br>2 - Ambulatory but unable to work<br>3 - Limited self-care | | | |

### End points reporting groups

| Reporting group title | Part 1 Arm A: DUR 1500 + LEN 20 |
|---|---|

Reporting group description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

| Reporting group title | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 |
|---|---|

Reporting group description:

Durvalumab (DUR) 1500mg IV infusion on Day 1 of Cycles 1 to 13 and lenalidomide (LEN) 20mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for subjects with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

| Reporting group title | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 |
|---|---|

Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m² IV infusion on Days 2, 8, 15, 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

| Reporting group title | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 1 Arm B: DUR 1500 + IBR 560 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 1 Arm C: DUR 1500 + RIT 375 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 1 Arm C: DUR 1500 + BEN 70 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

| Reporting group title | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 |
|---|---|

Reporting group description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received

durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 2 Arm B MCL: DUR 1500 + IBR 560 |
|---|---|

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| Reporting group title | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| Reporting group title | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 |
|---|---|

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 2 Arm D FL: DUR 1500 |
|---|---|

Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D CLL/SLL: DUR 1500 |
|---|---|

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D MCL: DUR 1500 |
|---|---|

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D HL: DUR 1500 |
|---|---|

Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Subject analysis set title | Part 1, Arm C: DUR 1500 mg + RIT 375 mg/mÂ² + BEN 90 mg/m² |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Subject analysis set title | Part 2, Arm B CLL/SLL: DUR 1500 mg + IBR 420 mG |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Subject analysis set title | Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m² |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| | |
|---|---|
| Subject analysis set title | Arm A: Durvalumab + Lenalidomide ± Rituximab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm B: Durvalumab + Ibrutinib |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm B received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 420 or 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Subject analysis set title | Arm C: Durvalumab + Bendamustine ± Rituximab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm C received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, 70 or 90 mg/m² bendamustine IV on Days 1 and 2 of Cycles 1 to 6, and rituximab 375 mg/m² IV on Day 2 of Cycles 1 to 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| | |
|---|---|
| Subject analysis set title | Arm D: Durvalumab Monotherapy |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

| | |
|---|---|
| Subject analysis set title | Arm D: Durvalumab Monotherapy |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm D received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13.

| | |
|---|---|
| Subject analysis set title | Arm A: Durvalumab + Lenalidomide Â± Rituximab |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm A received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and 10 mg or 20 mg lenalidomide orally once daily on Days 1 to 21 of Cycles 1 to 13 in indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in aggressive NHL, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm A: Lenalidomide 10 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants in Arm A received lenalidomide 10 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm A: Lenalidomide 20 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants in Arm A received lenalidomide 20 mg orally once daily on Days 1 to 21 of Cycles 1 to 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 to 13, and rituximab 375 mg/m² IV weekly in Cycle 1 and on Day 1 of Cycles 2 to 5.

| | |
|---|---|
| Subject analysis set title | Arm B: Ibrutinib 420 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm B received 420 mg ibrutinib orally once daily until disease progression,

unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

| | |
|---|---|
| Subject analysis set title | Arm B: Ibrutinib 560 mg |
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants assigned to Arm B received 560 mg ibrutinib orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason, and durvalumab 1500 mg IV on Day 1 of Cycles 1 to 13.

## Primary: Part 1: Number of Participants with Dose Limiting Toxicities (DLTs)

| | |
|---|---|
| End point title | Part 1: Number of Participants with Dose Limiting Toxicities (DLTs)[1][2] |

End point description:

Dose limiting toxicities were evaluated during the DLT evaluation period for participants in the dose finding cohorts. The severity grading was determined according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 4.03. A DLT is defined as below: Hematologic DLT • Grade 4 neutropenia observed for greater than 5 days duration • Grade 3 neutropenia associated with fever (≥ 38.5 °C) of any duration • Grade 4 thrombocytopenia or Grade 3 thrombocytopenia with bleeding, or any requirement for platelets transfusion • Grade 4 anemia, unexplained by underlying disease • Any other grade 4 hematologic toxicity that does not resolve to participant's pretreatment baseline level within 72 hours. Non-Hematologic DLT • Any non-hematological toxicity ≥ Grade 3 except for alopecia and nausea controlled by medical management • Any treatment interruption greater than 2 weeks due to adverse event.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

Cycle 1 (28 days)

Notes:

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

[2] - 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: Endpoints are cohort specific and do not report for all arms.

| **End point values** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 3 | 6 | 3 |
| Units: Participants | 0 | 3 | 1 | 0 |

| **End point values** | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 3 | 0[3] | 4 |
| Units: Participants | 0 | 0 | | 0 |

Notes:

[3] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN | | | |
|---|---|---|---|---|

| | 90 | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 5 | | | |
| Units: Participants | 1 | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants with Treatment-emergent Adverse Events

| End point title | Number of Participants with Treatment-emergent Adverse Events[4] |
|---|---|

End point description:

Treatment-emergent adverse events (TEAEs) are defined as adverse events (AEs) occurring or worsening on or after the first dose of any study treatment (durvalumab, lenalidomide, ibrutinib, bendamustine or rituximab) and within 90 days after last dose of durvalumab or 28 days after the last dose of other study drugs, whichever was later, as well as those serious adverse events made known to the investigator at any time thereafter that were suspected of being related to study treatment. The intensity of AEs was graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03. For all other AEs not described in the CTCAE criteria, the intensity was assessed by the investigator as mild (Grade 1), moderate (Grade 2), severe (Grade 3), life-threatening (Grade 4), or death (Grade 5).

| End point type | Primary |
|---|---|

End point timeframe:

From first dose of any study drug to 90 days after last dose of durvalumab or 28 days after last dose of other study drugs, up to the data cut-off date of 6 March 2019. Maximum time on treatment was 55.4 weeks for DUR and 130 weeks for other study drugs.

Notes:

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

| End point values | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 3 | 8 | 3 |
| Units: Participants | | | | |
| Any TEAE | 3 | 3 | 8 | 3 |
| TEAE Related to Any Study Drug | 3 | 3 | 8 | 3 |
| CTCAE Grade 3-4 TEAE | 1 | 3 | 7 | 2 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 1 | 3 | 7 | 1 |
| CTCAE Grade 5 TEAE | 0 | 0 | 0 | 0 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | 0 |
| Serious TEAE | 1 | 2 | 4 | 2 |
| Serious TEAE Related to Any Study Drug | 1 | 2 | 3 | 1 |
| TEAE Leading to Discontinuation of Any Study Drug | 1 | 0 | 3 | 1 |
| TEAE Leading to Dose Modifications of Study Drug | 1 | 3 | 3 | 3 |

| End point values | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 3 | 1 | 4 |
| Units: Participants | | | | |
| Any TEAE | 4 | 3 | 1 | 4 |
| TEAE Related to Any Study Drug | 4 | 3 | 0 | 4 |
| CTCAE Grade 3-4 TEAE | 3 | 2 | 1 | 3 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 1 | 2 | 0 | 2 |
| CTCAE Grade 5 TEAE | 0 | 0 | 0 | 0 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | 0 |
| Serious TEAE | 2 | 2 | 1 | 1 |
| Serious TEAE Related to Any Study Drug | 0 | 1 | 0 | 0 |
| TEAE Leading to Discontinuation of Any Study Drug | 0 | 0 | 0 | 0 |
| TEAE Leading to Dose Modifications of Study Drug | 4 | 3 | 1 | 4 |

| End point values | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 10 | 10 | 10 |
| Units: Participants | | | | |
| Any TEAE | 5 | 10 | 10 | 10 |
| TEAE Related to Any Study Drug | 5 | 10 | 9 | 10 |
| CTCAE Grade 3-4 TEAE | 4 | 8 | 10 | 6 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 2 | 7 | 6 | 5 |
| CTCAE Grade 5 TEAE | 0 | 0 | 1 | 0 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 1 | 0 |
| Serious TEAE | 3 | 6 | 7 | 5 |
| Serious TEAE Related to Any Study Drug | 1 | 2 | 3 | 3 |
| TEAE Leading to Discontinuation of Any Study Drug | 0 | 0 | 2 | 2 |
| TEAE Leading to Dose Modifications of Study Drug | 4 | 8 | 9 | 7 |

| End point values | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|---|---|---|

| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
|---|---|---|---|---|
| Number of subjects analysed | 10 | 5 | 5 | 10 |
| Units: Participants | | | | |
| Any TEAE | 9 | 5 | 5 | 9 |
| TEAE Related to Any Study Drug | 9 | 5 | 4 | 3 |
| CTCAE Grade 3-4 TEAE | 9 | 5 | 4 | 7 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 7 | 3 | 3 | 2 |
| CTCAE Grade 5 TEAE | 0 | 1 | 1 | 4 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | 0 |
| Serious TEAE | 5 | 2 | 4 | 7 |
| Serious TEAE Related to Any Study Drug | 3 | 1 | 3 | 1 |
| TEAE Leading to Discontinuation of Any Study Drug | 1 | 2 | 1 | 0 |
| TEAE Leading to Dose Modifications of Study Drug | 4 | 3 | 2 | 0 |

| **End point values** | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 2 | 5 | 5 | |
| Units: Participants | | | | |
| Any TEAE | 2 | 5 | 5 | |
| TEAE Related to Any Study Drug | 0 | 3 | 2 | |
| CTCAE Grade 3-4 TEAE | 1 | 4 | 3 | |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 0 | 1 | 1 | |
| CTCAE Grade 5 TEAE | 0 | 0 | 0 | |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | |
| Serious TEAE | 0 | 3 | 2 | |
| Serious TEAE Related to Any Study Drug | 0 | 0 | 0 | |
| TEAE Leading to Discontinuation of Any Study Drug | 0 | 1 | 0 | |
| TEAE Leading to Dose Modifications of Study Drug | 0 | 3 | 3 | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Overall Response Rate (ORR) During Durvalumab Treatment

| End point title | Overall Response Rate (ORR) During Durvalumab Treatment[5] |
|---|---|

End point description:

For lymphoma participants, response evaluation was based on International Working Group (IWG) response criteria for malignant lymphoma (the Lugano Classification). Overall response rate is defined as the percent of participants with best response of complete response (CR) or partial response (PR). For chronic lymphocytic leukemia participants, response evaluation was based on International Workshop on Chronic Lymphocytic Leukemia (IWCLL) guidelines for diagnosis and treatment of CLL. The

ORR is defined as the percent of participants with best response of CR, complete response with incomplete marrow recovery (CRi), nodular partial response (nPR), PR, or partial response with lymphocytosis (PRL).

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

End point timeframe:

Up to 13 cycles (12 months)

Notes:

[5] - 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: Endpoints are cohort specific and do not report for all arms.

| **End point values** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 3 | 5 | 3 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 33.3 (0.8 to 90.6) | 66.7 (9.4 to 99.2) | 80.0 (28.4 to 99.5) | 66.7 (9.4 to 99.2) |

| **End point values** | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 3 | 0[6] | 4 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 75.0 (19.4 to 99.4) | 33.3 (0.8 to 90.6) | ( to ) | 50.0 (6.8 to 93.2) |

Notes:

[6] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 9 | 10 | 9 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (-99999 to 99999) | 88.9 (51.8 to 99.7) | 60.0 (26.2 to 87.8) | 88.9 (51.8 to 99.7) |

| **End point values** | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 | Part 2 Arm D CLL/SLL: DUR 1500 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 5 | 10 | 2 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 50.0 (6.8 to 93.2) | 0 (-99999 to 99999) | 0 (-99999 to 99999) | 0 (-99999 to 99999) |

| End point values | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | Part 2 Arm C DLBCL: DUR + RIT 375 mg/m² + BEN 70 mg/m² | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 5 | 5 | 10 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (-99999 to 99999) | 20.0 (0.5 to 71.6) | 30.0 (6.7 to 65.2) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Overall Response Rate During the Entire Study

| End point title | Overall Response Rate During the Entire Study |
|---|---|

End point description:

For lymphoma participants, response evaluation was based on International Working Group (IWG) response criteria for malignant lymphoma (the Lugano Classification) (Cheson, 2014). Overall response rate is defined as the percent of participants with best response of complete response (CR) or partial response (PR). For chronic lymphocytic leukemia participants, response evaluation was based on International Workshop on Chronic Lymphocytic Leukemia (IWCLL) guidelines for diagnosis and treatment of CLL. The ORR is defined as the percentage of participants with best response of CR, complete response with incomplete marrow recovery (CRi), nodular partial response (nPR), PR, or partial response with lymphocytosis (PRL).

-99999/99999 = Not Available

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

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

| End point values | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 3 | 5 | 3 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 66.7 (9.4 to 99.2) | 66.7 (9.4 to 99.2) | 80.0 (28.4 to 99.5) | 66.7 (9.4 to 99.2) |

| End point values | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 |
|---|---|---|---|---|

| | | | | +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 3 | 0[7] | 4 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 75.0 (19.4 to 99.4) | 33.3 (0.8 to 90.6) | ( to ) | 50.0 (6.8 to 93.2) |

Notes:

[7] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 9 | 10 | 9 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (-99999 to 99999) | 100.0 (66.4 to 100.0) | 70.0 (34.8 to 93.3) | 88.9 (51.8 to 99.7) |

| **End point values** | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 4 | 5 | 10 |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 30.0 (6.7 to 65.2) | 50.0 (6.8 to 93.2) | 0 (-99999 to 99999) | 0 (-99999 to 99999) |

| **End point values** | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 2 | 5 | 5 | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 0 (-99999 to 99999) | 0 (-99999 to 99999) | 20.0 (0.5 to 71.6) | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Time to First Response

| End point title | Time to First Response |
|---|---|

End point description:

Time to response was calculated as the time from first dose of study drug to the first response date (CR or PR for lymphoma participants and CR, CRi, nPR, PR, or PRL for CLL participants).

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

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

| **End point values** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 2 | 4 | 2 |
| Units: weeks | | | | |
| median (full range (min-max)) | 70.85 (12.1 to 129.6) | 12.60 (12.1 to 13.1) | 18.20 (11.3 to 36.1) | 11.85 (11.4 to 12.3) |

| **End point values** | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 1 | 0[8] | 2 |
| Units: weeks | | | | |
| median (full range (min-max)) | 13.40 (12.4 to 52.9) | 13.00 (13.0 to 13.0) | ( to ) | 13.10 (12.1 to 14.1) |

Notes:

[8] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[9] | 9 | 7 | 8 |
| Units: weeks | | | | |
| median (full range (min-max)) | ( to ) | 12.10 (10.9 to 72.9) | 12.10 (6.6 to 26.4) | 12.35 (10.3 to 15.3) |

Notes:

[9] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 2 | 0[10] | 0[11] |
| Units: weeks | | | | |
| median (full range (min-max)) | 12.00 (8.7 to 12.1) | 12.10 (12.1 to 12.1) | ( to ) | ( to ) |

Notes:

[10] - Unable to calculate due to insufficient number of events.

[11] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[12] | 0[13] | 1 | |
| Units: weeks | | | | |
| median (full range (min-max)) | ( to ) | ( to ) | 13.10 (13.1 to 13.1) | |

Notes:

[12] - Unable to calculate due to insufficient number of events.

[13] - Unable to calculate due to insufficient number of events.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Kaplan-Meier Estimate of Duration of response

| End point title | Kaplan-Meier Estimate of Duration of response |
|---|---|

End point description:

Duration of response is defined for responders only as the time from the first documented response (CR or PR for lymphoma participants or CR, CRi, nPR, PR, or PRL for CLL participants) to disease progression or death (from any cause). For participants with response but no progression, or death, duration of response was censored at the last date that the participant was known to be progression-free.

-99999/99999 = Not Available

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

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

| **End point values** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 2 | 2 | 4 | 2 |
| Units: weeks | | | | |
| median (confidence interval 95%) | 10.14 (-99999 to 99999) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) |

| **End point values** | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 1 | 0[14] | 2 |
| Units: weeks | | | | |

| | | | | |
|---|---|---|---|---|
| median (confidence interval 95%) | 99999 (-99999 to 99999) | 29.29 (-99999 to 99999) | ( to ) | 99999 (-99999 to 99999) |

Notes:

[14] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[15] | 9 | 7 | 8 |
| Units: weeks | | | | |
| median (confidence interval 95%) | ( to ) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) |

Notes:

[15] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 2 | 0[16] | 0[17] |
| Units: weeks | | | | |
| median (confidence interval 95%) | 24.14 (9.14 to 26.14) | 99999 (-99999 to 99999) | ( to ) | ( to ) |

Notes:

[16] - Unable to calculate due to insufficient number of events.

[17] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[18] | 0[19] | 1 | |
| Units: weeks | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | 11.14 (-99999 to 99999) | |

Notes:

[18] - Unable to calculate due to insufficient number of events.

[19] - Unable to calculate due to insufficient number of events.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Kaplan-Meier Estimate of Progression-free Survival (PFS)

| | |
|---|---|
| End point title | Kaplan-Meier Estimate of Progression-free Survival (PFS) |

End point description:

Progression-free survival was calculated as the time from first dose of study drug to the first documented progression or death (from any cause) during the entire efficacy evaluation period. For participants with no progression or death, PFS was censored at the last assessment date the participant was known to be progression-free.

-99999/99999 = Not Available

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

End point timeframe:

From first dose of any study drug to the end of follow-up, up to the data cutoff date of March 6, 2019; median (minimum, maximum) time on study was 16.7 (0.9, 32.9) months.

| **End point values** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 3 | 8 | 3 |
| Units: months | | | | |
| median (confidence interval 95%) | 8.41 (5.09 to 99999) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) |

| **End point values** | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 3 | 1 | 4 |
| Units: months | | | | |
| median (confidence interval 95%) | 28.71 (4.50 to 99999) | 9.69 (1.64 to 12.68) | 1.25 (-99999 to 99999) | 3.82 (1.25 to 99999) |

| **End point values** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 10 | 10 | 10 |
| Units: months | | | | |
| median (confidence interval 95%) | 2.48 (0.49 to 5.91) | 99999 (-99999 to 99999) | 99999 (-99999 to 99999) | 14.65 (5.75 to 14.65) |

| **End point values** | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 5 | 5 | 10 |
| Units: months | | | | |
| median (confidence interval 95%) | 2.06 (0.76 to 8.28) | 99999 (-99999 to 99999) | 1.68 (0.69 to 4.63) | 1.17 (0.26 to 3.19) |

| End point values | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 2 | 5 | 5 | |
| Units: months | | | | |
| median (confidence interval 95%) | 2.76 (2.50 to 3.02) | 2.33 (0.79 to 10.02) | 2.66 (2.56 to 5.98) | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Maximum Plasma Concentration (Tmax) of Durvalumab

| End point title | Time to Maximum Plasma Concentration (Tmax) of Durvalumab |
|---|---|

End point description:

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

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

| End point values | Arm A: Durvalumab + Lenalidomide ± Rituximab | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab | Arm D: Durvalumab Monotherapy |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 14 | 27 | 38 | 26 |
| Units: days | | | | |
| median (full range (min-max)) | 0.0510 (0.042 to 1.035) | 0.0479 (0.041 to 1.061) | 0.0510 (0.042 to 6.788) | 0.0420 (0.038 to 1.986) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Observed Plasma Concentration (Cmax) of Durvalumab

| End point title | Maximum Observed Plasma Concentration (Cmax) of Durvalumab |
|---|---|

End point description:

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

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

| End point values | Arm A: Durvalumab + Lenalidomide ± Rituximab | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab | Arm D: Durvalumab Monotherapy |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 14 | 27 | 38 | 26 |
| Units: µg/L | | | | |
| geometric mean (geometric coefficient of variation) | 420264.066 (± 22.7) | 361906.229 (± 30.1) | 331572.478 (± 33.4) | 392663.668 (± 41.1) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Plasma Concentration-time Curve From Time zero to Infinity (AUCinf) of Durvalumab

| End point title | Area Under the Plasma Concentration-time Curve From Time zero to Infinity (AUCinf) of Durvalumab |
|---|---|

End point description:

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

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

| End point values | Arm A: Durvalumab + Lenalidomide ± Rituximab | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab | Arm D: Durvalumab Monotherapy |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 14 | 27 | 38 | 25 |
| Units: days*µg/L | | | | |
| geometric mean (geometric coefficient of variation) | 4867431.378 (± 23.3) | 5818262.846 (± 42.1) | 4762968.345 (± 71.0) | 5593532.553 (± 53.0) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Durvalumab

| End point title | Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Durvalumab |
|---|---|

End point description:

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

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

| **End point values** | Arm A: Durvalumab + Lenalidomide ± Rituximab | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab | Arm D: Durvalumab Monotherapy |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 14 | 27 | 38 | 26 |
| Units: days*µg/L | | | | |
| geometric mean (geometric coefficient of variation) | 3120149.759 (± 29.5) | 3225869.344 (± 31.9) | 2670168.397 (± 46.7) | 3053060.746 (± 37.8) |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Terminal Elimination Phase Half-Life (t½) of Durvalumab**

| End point title | Terminal Elimination Phase Half-Life (t½) of Durvalumab |
|---|---|

End point description:

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

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

| **End point values** | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab | Arm D: Durvalumab Monotherapy | Arm A: Durvalumab + Lenalidomide Â± Rituximab |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 27 | 38 | 25 | 14 |
| Units: days | | | | |
| geometric mean (geometric coefficient of variation) | 17.344 (± 47.3) | 16.327 (± 57.4) | 15.399 (± 53.5) | 11.596 (± 46.6) |

**Statistical analyses**

No statistical analyses for this end point

## Secondary: Clearance (CL) of Durvalumab

| End point title | Clearance (CL) of Durvalumab |
|---|---|

End point description:

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

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

| End point values | Arm A: Durvalumab + Lenalidomide ± Rituximab | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab | Arm D: Durvalumab Monotherapy |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 14 | 27 | 38 | 25 |
| Units: L/day | | | | |
| geometric mean (geometric coefficient of variation) | 0.3082 (± 23.3) | 0.2578 (± 42.1) | 0.3149 (± 71.0) | 0.2682 (± 53.0) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Volume of Distribution (Vz) of Durvalumab

| End point title | Volume of Distribution (Vz) of Durvalumab |
|---|---|

End point description:

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

End point timeframe:

Cycle 1, Day 1 (pre-dose and at end of infusion), and 4, 24, 48, 168 (Day 8), 336 (Day 15), and 508 (Day 22) hours after the end of infusion.

| End point values | Arm A: Durvalumab + Lenalidomide ± Rituximab | Arm B: Durvalumab + Ibrutinib | Arm C: Durvalumab + Bendamustine ± Rituximab | Arm D: Durvalumab Monotherapy |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 14 | 27 | 38 | 25 |
| Units: liters | | | | |
| geometric mean (geometric coefficient of variation) | 5.155 (± 41.9) | 6.451 (± 38.3) | 7.418 (± 33.7) | 5.957 (± 33.0) |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Observed Plasma Concentration (Cmax) of Lenalidomide

| End point title | Maximum Observed Plasma Concentration (Cmax) of Lenalidomide |
|---|---|

End point description:

99999 = Not Available

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

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

| **End point values** | Arm A: Lenalidomide 10 mg | Arm A: Lenalidomide 20 mg | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 5 | 4 | | |
| Units: ng/mL | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cycle 1 Day 1 | 141.881 (± 22.0) | 309.917 (± 6.9) | | |
| Cycle 1 Day 15 | 107.635 (± 40.9) | 174.090 (± 99999) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Maximum Observed Plasma Concentration (Tmax) of Lenalidomide

| End point title | Time to Maximum Observed Plasma Concentration (Tmax) of Lenalidomide |
|---|---|

End point description:

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

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

| End point values | Arm A: Lenalidomide 10 mg | Arm A: Lenalidomide 20 mg | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 5 | 4 | | |
| Units: hours | | | | |
| median (full range (min-max)) | | | | |
| Cycle 1 Day 1 | 1.9500 (1.000 to 3.917) | 1.1667 (1.000 to 1.433) | | |
| Cycle 1 Day 15 | 3.0333 (1.233 to 4.000) | 1.000 (1.000 to 1.000) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Lenalidomide

| End point title | Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Lenalidomide |
|---|---|

End point description:

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

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose

| End point values | Arm A: Lenalidomide 10 mg | Arm A: Lenalidomide 20 mg | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 5 | 4 | | |
| Units: h*ng/mL | | | | |
| geometric mean (geometric coefficient of variation) | 789.297 (± 84.3) | 805.299 (± 56.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Maximum Observed Plasma Concentration (Cmax) of Ibrutinib

| End point title | Maximum Observed Plasma Concentration (Cmax) of Ibrutinib |
|---|---|

End point description:

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

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2,

and 4 hours post-dose.

| End point values | Arm B: Ibrutinib 420 mg | Arm B: Ibrutinib 560 mg | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 13 | 13 | | |
| Units: ng/mL | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| Cycle 1 Day 1 | 129.704 (± 98.0) | 67.728 (± 197.9) | | |
| Cycle 1 Day 15 | 86.840 (± 136.9) | 72.436 (± 166.3) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Ibrutinib

| End point title | Area Under the Plasma Concentration-time Curve from Time Zero to the Last Measurable Concentration (AUClast) of Ibrutinib |
|---|---|

End point description:

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

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose

| End point values | Arm B: Ibrutinib 420 mg | Arm B: Ibrutinib 560 mg | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 13 | 13 | | |
| Units: h*ng/mL | | | | |
| geometric mean (geometric coefficient of variation) | 586.396 (± 117.2) | 436.855 (± 246.5) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline in Soluble Programmed Cell Death Ligand-1 (sPD-

## L1) Concentration

| End point title | Change from Baseline in Soluble Programmed Cell Death Ligand-1 (sPD-L1) Concentration |
|---|---|

End point description:

Change from baseline in sPD-L1 could not be calculated as all post-baseline samples were below the lower limit of quantification (<15.60 pg/mL).

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

End point timeframe:

Baseline (Cycle 1 Day 1 predose) and Day 1 of Cycles 2 to 13

| **End point values** | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[20] | 0[21] | 0[22] | 0[23] |
| Units: pg/mL | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[20] - Unable to calculate due to insufficient number of events.

[21] - Unable to calculate due to insufficient number of events.

[22] - Unable to calculate due to insufficient number of events.

[23] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[24] | 0[25] | 0[26] | 0[27] |
| Units: pg/mL | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[24] - Unable to calculate due to insufficient number of events.

[25] - Unable to calculate due to insufficient number of events.

[26] - Unable to calculate due to insufficient number of events.

[27] - Unable to calculate due to insufficient number of events.

| **End point values** | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[28] | 0[29] | 0[30] | 0[31] |
| Units: pg/mL | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[28] - Unable to calculate due to insufficient number of events.

[29] - Unable to calculate due to insufficient number of events.

[30] - Unable to calculate due to insufficient number of events.

[31] - Unable to calculate due to insufficient number of events.

| End point values | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[32] | 0[33] | 0[34] | 0[35] |
| Units: pg/mL | | | | |
| arithmetic mean (standard deviation) | () | () | () | () |

Notes:

[32] - Unable to calculate due to insufficient number of events.

[33] - Unable to calculate due to insufficient number of events.

[34] - Unable to calculate due to insufficient number of events.

[35] - Unable to calculate due to insufficient number of events.

| End point values | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 0[36] | 0[37] | 0[38] | |
| Units: pg/mL | | | | |
| arithmetic mean (standard deviation) | () | () | () | |

Notes:

[36] - Unable to calculate due to insufficient number of events.

[37] - Unable to calculate due to insufficient number of events.

[38] - Unable to calculate due to insufficient number of events.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Maximum Observed Plasma Concentration (Tmax) of Ibrutinib

| End point title | Time to Maximum Observed Plasma Concentration (Tmax) of Ibrutinib |
|---|---|

End point description:

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

End point timeframe:

Cycle 1 Day 1 at predose and 1, 2, 4, and 24 hours post-dose, and Cycle 1 Day 15 at pre-dose, 1, 2, and 4 hours post-dose.

| End point values | Arm B: Ibrutinib 420 mg | Arm B: Ibrutinib 560 mg | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 13 | 13 | | |
| Units: hours | | | | |
| median (full range (min-max)) | | | | |
| Cycle 1 Day 1 | 2.000 (0.000 to 4.367) | 1.9333 (0.933 to 3.917) | | |
| Cycle 1 Day 15 | 1.8833 (1.000 to 4.000) | 2.000 (1.000 to 4.083) | | |

## Statistical analyses

No statistical analyses for this end point

## Post-hoc: Number of Participants with Treatment-emergent Adverse Events (TEAEs) - Extended Collection

| End point title | Number of Participants with Treatment-emergent Adverse Events (TEAEs) - Extended Collection |
|---|---|

End point description:

TEAEs defined as AEs occurring or worsening on or after first dose of any study treatment (durvalumab, lenalidomide, ibrutinib, bendamustine or rituximab) and within 90 days after last dose of durvalumab or 28 days after the last dose of other study drugs, whichever was later, as well as those serious adverse events made known to the investigator at any time thereafter that were suspected of being related to study treatment. Intensity of AEs graded according to the NCI CTCAE V. 4.03. For all other AEs not described in the CTCAE criteria, the intensity was assessed by investigator as mild (Grade 1), moderate (Grade 2), severe (Grade 3), life-threatening (Grade 4), or death (Grade 5). This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date (assessments made until August 21, 2022).

| End point type | Post-hoc |
|---|---|

End point timeframe:

From first dose of any study drug to 90 days after last dose of durvalumab or 28 days after last dose of other study drugs, up to the study completion date of August 21, 2022 (up to approximately 75 months).

| End point values | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm A: DUR 1500 +LEN 20 +RIT 375 | Part 1 Arm A: DUR 1500 +LEN 10 +RIT 375 | Part 1 Arm B: DUR 1500 + IBR 420 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 3 | 8 | 3 |
| Units: Participants | | | | |
| Any TEAE | 3 | 3 | 8 | 3 |
| TEAE Related to Any Study Drug | 3 | 3 | 8 | 3 |
| CTCAE Grade 3-4 TEAE | 1 | 3 | 7 | 2 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 1 | 3 | 7 | 1 |
| CTCAE Grade 5 TEAE | 0 | 0 | 0 | 0 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | 0 |
| Serious TEAE | 1 | 2 | 4 | 2 |
| Serious TEAE Related to Any Study Drug | 1 | 2 | 3 | 1 |
| TEAE Leading to Discontinuation of Any Study Drug | 1 | 0 | 3 | 1 |
| TEAE Leading to Dose Modifications of Study Drug | 1 | 3 | 5 | 3 |

| End point values | Part 1 Arm B: DUR 1500 + IBR 560 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 +RIT 375 +BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 4 | 3 | 1 | 4 |
| Units: Participants | | | | |
| Any TEAE | 4 | 3 | 1 | 4 |
| TEAE Related to Any Study Drug | 4 | 3 | 0 | 4 |
| CTCAE Grade 3-4 TEAE | 4 | 2 | 1 | 3 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 1 | 2 | 0 | 2 |
| CTCAE Grade 5 TEAE | 0 | 0 | 0 | 0 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | 0 |
| Serious TEAE | 3 | 2 | 1 | 1 |
| Serious TEAE Related to Any Study Drug | 0 | 1 | 0 | 0 |
| TEAE Leading to Discontinuation of Any Study Drug | 0 | 0 | 0 | 0 |
| TEAE Leading to Dose Modifications of Study Drug | 4 | 3 | 1 | 4 |

| End point values | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 10 | 10 | 10 |
| Units: Participants | | | | |
| Any TEAE | 5 | 10 | 10 | 10 |
| TEAE Related to Any Study Drug | 5 | 10 | 9 | 10 |
| CTCAE Grade 3-4 TEAE | 4 | 9 | 10 | 6 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 2 | 8 | 6 | 5 |
| CTCAE Grade 5 TEAE | 0 | 0 | 1 | 0 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 1 | 0 |
| Serious TEAE | 3 | 6 | 7 | 5 |
| Serious TEAE Related to Any Study Drug | 1 | 3 | 3 | 3 |
| TEAE Leading to Discontinuation of Any Study Drug | 0 | 0 | 2 | 2 |
| TEAE Leading to Dose Modifications of Study Drug | 4 | 9 | 9 | 7 |

| End point values | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C CLL/SLL:DUR 1500 +RIT 375 +BEN 70 | Part 2 Arm D FL: DUR 1500 | Part 2 Arm D DLBCL: DUR 1500 |
|---|---|---|---|---|

| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
|---|---|---|---|---|
| Number of subjects analysed | 10 | 5 | 5 | 10 |
| Units: Participants | | | | |
| Any TEAE | 9 | 5 | 5 | 9 |
| TEAE Related to Any Study Drug | 9 | 5 | 4 | 3 |
| CTCAE Grade 3-4 TEAE | 9 | 5 | 4 | 7 |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 7 | 3 | 3 | 2 |
| CTCAE Grade 5 TEAE | 0 | 1 | 1 | 4 |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | 0 |
| Serious TEAE | 5 | 2 | 4 | 7 |
| Serious TEAE Related to Any Study Drug | 3 | 1 | 3 | 1 |
| TEAE Leading to Discontinuation of Any Study Drug | 1 | 2 | 1 | 0 |
| TEAE Leading to Dose Modifications of Study Drug | 4 | 3 | 2 | 0 |

| **End point values** | Part 2 Arm D CLL/SLL: DUR 1500 | Part 2 Arm D MCL: DUR 1500 | Part 2 Arm D HL: DUR 1500 | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 2 | 5 | 5 | |
| Units: Participants | | | | |
| Any TEAE | 2 | 5 | 5 | |
| TEAE Related to Any Study Drug | 0 | 3 | 2 | |
| CTCAE Grade 3-4 TEAE | 1 | 4 | 3 | |
| CTCAE Grade 3-4 TEAE Related to Any Study Drug | 0 | 1 | 1 | |
| CTCAE Grade 5 TEAE | 0 | 0 | 0 | |
| CTCAE Grade 5 TEAE Related to Any Study Drug | 0 | 0 | 0 | |
| Serious TEAE | 0 | 3 | 2 | |
| Serious TEAE Related to Any Study Drug | 0 | 0 | 0 | |
| TEAE Leading to Discontinuation of Any Study Drug | 0 | 1 | 0 | |
| TEAE Leading to Dose Modifications of Study Drug | 0 | 3 | 3 | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events information

Timeframe for reporting adverse events:

SAEs and NSAEs assessed from first dose to 90 days from last dose of durva or 28 days from last dose of lenalidomide, ibrutinib, rituximab, bendamustine, or IFRT, whichever occurs later (up to approximately 75 months)

| | |
|---|---|
| Assessment type | Systematic |

## Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 22.0 |

## Reporting groups

| | |
|---|---|
| Reporting group title | Part 1 Arm A: DUR 1500 + LEN 20 + RIT 375 |

Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab (RIT) 375 mg/m² IV infusion on Days 2, 8, 15, and 22 of Cycle 1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

| | |
|---|---|
| Reporting group title | Part 1 Arm A: DUR 1500 + LEN 20 |

Reporting group description:

Participants received durvalumab (DUR) 1500 mg intravenous (IV) infusion on Day 1 of Cycles 1 through 13 (ie, 12 months) and lenalidomide (LEN) 20 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent non-Hodgkin's lymphoma (NHL) or for all cycles of treatment period until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL.

| | |
|---|---|
| Reporting group title | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 70 |

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| | |
|---|---|
| Reporting group title | Part 1 Arm C: DUR 1500 + BEN 70 |

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and bendamustine (BEN) 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6.

| | |
|---|---|
| Reporting group title | Part 1 Arm C: DUR 1500 + RIT 375 |

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for participants with CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| | |
|---|---|
| Reporting group title | Part 1 Arm B: DUR 1500 + IBR 560 |

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Reporting group title | Part 1 Arm B: DUR 1500 + IBR 420 |

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib (IBR) 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| | |
|---|---|
| Reporting group title | Part 1 Arm A: DUR 1500 + LEN 10 + RIT 375 |

Reporting group description:

Participants received durvalumab (DUR) 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and lenalidomide (LEN) 10 mg orally once daily on Days 1 to 21 of Cycles 1 through 13 for participants with indolent NHL or until disease progression, unacceptable toxicity, or discontinuation for any other reason in participants with aggressive NHL, and rituximab 375 mg/m² IV infusion on Days 2, 8, 15, 22 of Cycle

1 and on Day 1 of every 28-day cycle from Cycles 2 through 5.

| Reporting group title | Part 2, Arm D CLL/SLL: DUR 1500 mg |
|---|---|

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2, Arm D MCL: DUR 1500 mg |
|---|---|

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2, Arm D DLBCL: DUR 1500 mg |
|---|---|

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm D FL: DUR 1500 |
|---|---|

Reporting group description:

Participants with follicular lymphoma received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 2 Arm C CLL/SLL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Reporting group description:

Participants with CLL or SLL received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Reporting group description:

Participants with diffuse large B-cell lymphoma (DLBCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| Reporting group title | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|

Reporting group description:

Participants with follicular lymphoma (FL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 70 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6.

| Reporting group title | Part 2 Arm B MCL: DUR 1500 + IBR 560 |
|---|---|

Reporting group description:

Participants with mantle cell lymphoma (MCL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 560 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| Reporting group title | Part 2, Arm D HL: DUR 1500 mg |
|---|---|

Reporting group description:

Participants with Hodgkin lymphoma (HL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13.

| Reporting group title | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|

Reporting group description:

Participants received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13, bendamustine 90 mg/m² IV infusion on Days 1 and 2 of Cycles 1 through 6, and rituximab 375 mg/m² IV infusion on Day 2 of Cycles 1 through 6 (for CLL the rituximab dose was 375 mg/m² Cycle 1 first dose and 500 mg/m² for each subsequent dose).

| Reporting group title | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 |
|---|---|

Reporting group description:

Participants with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) received durvalumab 1500 mg IV infusion on Day 1 of Cycles 1 through 13 and ibrutinib 420 mg orally once daily until disease progression, unacceptable toxicity or discontinuation for any other reason.

| **Serious adverse events** | Part 1 Arm A: DUR 1500 + LEN 20 + RIT 375 | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| number of deaths (all causes) | 1 | 1 | 3 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 | | | |
| Jugular vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Superior vena cava syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (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 |
| Pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Organising pneumonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (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 |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (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 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aptyalism | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal perforation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenic sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural infection bacterial | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (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 |
| Skin infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 device infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm B: DUR 1500 + IBR 560 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 2 / 3 (66.67%) | 3 / 4 (75.00%) |
| number of deaths (all causes) | 1 | 2 | 3 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 | | | |
| Jugular vein thrombosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Superior vena cava syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (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 |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Organising pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytopenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aptyalism | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| 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 dysplasia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal perforation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenic sepsis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural infection bacterial | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| 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 device infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Part 1 Arm B: DUR 1500 + IBR 420 | Part 1 Arm A: DUR 1500 + LEN 10 + RIT 375 | Part 2, Arm D CLL/SLL: DUR 1500 mg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 4 / 8 (50.00%) | 0 / 2 (0.00%) |
| number of deaths (all causes) | 0 | 2 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate cancer | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| Jugular vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Superior vena cava syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Organising pneumonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (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 |
| Syncope | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (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 |
| Neutropenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aptyalism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal perforation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| 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 | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (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 |
| Bronchitis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (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 |
| Neutropenic sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural infection bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (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 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| 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 device infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Part 2, Arm D MCL: DUR 1500 mg | Part 2, Arm D DLBCL: DUR 1500 mg | Part 2 Arm D FL: DUR 1500 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 5 (80.00%) | 8 / 10 (80.00%) | 4 / 5 (80.00%) |
| number of deaths (all causes) | 4 | 9 | 4 |
| number of deaths resulting from adverse events | 0 | 4 | 2 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Jugular vein thrombosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Superior vena cava syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 2 / 10 (20.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (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 |
| Pyrexia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Organising pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (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 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (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 |
| Myocardial infarction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancytopenia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (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 |
| Thrombocytopenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aptyalism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal perforation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Haematemesis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| 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 haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenic sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural infection bacterial | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (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 |
| Septic shock | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Part 2 Arm C | Part 2 Arm C DLBCL: | Part 2 Arm C FL: |
|---|---|---|---|

| | CLL/SLL: DUR 1500 + RIT 375 + BEN 70 | DUR 1500 + RIT 375 + BEN 70 | DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 5 / 10 (50.00%) | 5 / 10 (50.00%) |
| number of deaths (all causes) | 2 | 9 | 0 |
| number of deaths resulting from adverse events | 1 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| 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 | | | |
| Jugular vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Superior vena cava syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (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 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (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 |
| Pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Organising pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aptyalism | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal perforation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| 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 | | | |
| Adrenal insufficiency | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| 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 | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (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 sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural infection bacterial | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (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 |
| Skin infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| 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 device infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2, Arm D HL: DUR 1500 mg | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 10 (70.00%) | 2 / 5 (40.00%) | 3 / 5 (60.00%) |
| number of deaths (all causes) | 2 | 4 | 4 |
| number of deaths resulting from adverse events | 1 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (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 |
| Prostate cancer | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of lung | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Jugular vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (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 |
| Superior vena cava syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| 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 physical health deterioration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Multiple organ dysfunction syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 5 (40.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Cytokine release syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Organising pneumonia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (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 |
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac failure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebral ischaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cytopenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aptyalism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colon dysplasia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastric haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal perforation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| 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 | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenic sepsis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural infection bacterial | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Septic shock | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| 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 infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcal infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| 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 device infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 10 (60.00%) | | |
| number of deaths (all causes) | 1 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Prostate cancer | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Squamous cell carcinoma of skin | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Squamous cell carcinoma of lung | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vascular disorders | | | | |
| Jugular vein thrombosis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypotension | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Superior vena cava syndrome | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| General disorders and administration site conditions | | | | |
| Asthenia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| General physical health deterioration | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Malaise | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|---|---|---|---|---|
| Generalised oedema | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Multiple organ dysfunction syndrome | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyrexia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Immune system disorders | | | | |
| Cytokine release syndrome | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Dyspnoea | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Organising pneumonia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleural effusion | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | |
|---|---|---|---|
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Investigations | | | |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General physical condition abnormal | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Post procedural haemorrhage | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac disorders | | | |
| Acute coronary syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Atrial fibrillation | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac failure | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Myocardial infarction | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders | | | | |
| Cerebral ischaemia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Syncope | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Blood and lymphatic system disorders | | | | |
| Anaemia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cytopenia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Febrile neutropenia | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neutropenia | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancytopenia | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Thrombocytopenia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal disorders | | | | |
| Abdominal pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Aptyalism | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Abdominal wall haematoma | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diarrhoea | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Colon dysplasia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastric haemorrhage | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal perforation | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haematemesis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rectal haemorrhage | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Small intestinal haemorrhage | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Small intestinal obstruction | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vomiting | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatobiliary disorders | | | | |
| Hepatitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hyperbilirubinaemia | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Drug reaction with eosinophilia and systemic symptoms | | | |
| subjects affected / exposed | 0 / 10 (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 | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Endocrine disorders | | | |
| Adrenal insufficiency | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis viral | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower respiratory tract infection viral | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lung infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Neutropenic sepsis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Parainfluenzae virus infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleural infection bacterial | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Septic shock | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sinusitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Streptococcal infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vascular device infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metabolism and nutrition disorders | | | | |
| Dehydration | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| **Non-serious adverse events** | Part 1 Arm A: DUR 1500 + LEN 20 + RIT 375 | Part 1 Arm A: DUR 1500 + LEN 20 | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 3 / 3 (100.00%) | 4 / 4 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Tumour flare | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aortic stenosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Shock | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Asthenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General physical health deterioration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 2 / 3 (66.67%) | 1 / 4 (25.00%) |
| occurrences (all) | 3 | 3 | 1 |
| Early satiety | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 1 | 2 |
| Discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gravitational oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Inflammation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumatosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **Reproductive system and breast disorders** | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngeal inflammation | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoxia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinus disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Rales | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Apathy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiovascular somatic symptom disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 4 |
| Disorientation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood bilirubin increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunoglobulins decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| White blood cell count decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood uric acid increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Monocyte count increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Overdose | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Allergic transfusion reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Neck injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Epidermolysis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pericardial disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus bradycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Aphasia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 3 | 1 | 2 |
| Tremor | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amnesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensory disturbance | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 3 (66.67%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 0 | 3 |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 2 / 4 (50.00%) |
| occurrences (all) | 4 | 3 | 4 |

| | | | |
|---|---|---|---|
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 2 | 0 | 3 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone marrow failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear discomfort | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Blepharitis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Retinopathy hypertensive | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid ptosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iritis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous detachment | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 2 | 1 |
| Constipation | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 3 / 3 (100.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 3 | 7 | 1 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 0 | 3 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Dysphagia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 1 | 2 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal fissure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Toothache | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis exfoliative generalised | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 2 | 0 | 2 |
| Erythema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin fissures | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychoclasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neurodermatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Purpura | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Micturition urgency | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 3 (66.67%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal impairment | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Urinary tract pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thyroiditis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 1 | 1 | 3 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscle discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 2 / 3 (66.67%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Arthritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle mass | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb mass | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint noise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Folliculitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lip infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Otitis externa | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes ophthalmic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Human herpesvirus 6 infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stenotrophomonas sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prostate infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection viral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Dehydration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 2 / 3 (66.67%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Hyperlactacidaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gout | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polydipsia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Part 1 Arm C: DUR 1500 + BEN 70 | Part 1 Arm C: DUR 1500 + RIT 375 | Part 1 Arm B: DUR 1500 + IBR 560 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 3 / 3 (100.00%) | 4 / 4 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour flare | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Aortic stenosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Shock | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Influenza like illness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Early satiety | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gravitational oedema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Inflammation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumatosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Penile oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 1 | 4 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Laryngeal inflammation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinus disorder | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hiccups | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rales | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Wheezing | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Apathy | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiovascular somatic symptom disorder | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disorientation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunoglobulins decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood uric acid increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Monocyte count increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Overdose | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic transfusion reaction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Neck injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thermal burn | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Epidermolysis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pericardial disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus bradycardia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Aphasia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Tremor | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amnesia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Memory impairment | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensory disturbance | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 4 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Neutropenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone marrow failure | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye disorders | | | |

| | | | |
|---|---|---|---|
| Blepharitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Retinopathy hypertensive | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eyelid disorder | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid ptosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Iritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital oedema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Vision blurred | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous detachment | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 1 | 5 |
| Constipation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 3 / 4 (75.00%) |
| occurrences (all) | 0 | 1 | 3 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 1 | 3 |
| Dyspepsia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Anal fissure | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Ascites | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Lip haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis exfoliative generalised | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 4 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Rash | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 1 | 4 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin fissures | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Alopecia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychoclasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Neurodermatitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Purpura | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Micturition urgency | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Renal impairment | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 4 |
| Back pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Neck pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle mass | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb mass | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint noise | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 2 / 3 (66.67%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 4 | 1 |

| | | | |
|---|---|---|---|
| Cystitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Lip infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin infection | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Tooth infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 2 / 4 (50.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 2 | 4 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 1 / 3 (33.33%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bacterial sepsis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Herpes ophthalmic | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hordeolum | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Human herpesvirus 6 infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stenotrophomonas sepsis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prostate infection | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection viral | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 1 / 4 (25.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlactacidaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gout | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polydipsia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | 0 / 3 (0.00%) | 0 / 4 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Part 1 Arm B: DUR 1500 + IBR 420 | Part 1 Arm A: DUR 1500 + LEN 10 + RIT 375 | Part 2, Arm D CLL/SLL: DUR 1500 mg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 8 / 8 (100.00%) | 2 / 2 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour flare | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aortic stenosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Shock | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 2 / 2 (100.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Early satiety | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 8 (25.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 2 | 2 |
| Discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gravitational oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Inflammation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumatosis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 8 (37.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasal congestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngeal inflammation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinus disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic obstructive pulmonary | | | |

| | | | |
|---|---|---|---|
| disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Rales | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Apathy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 2 / 3 (66.67%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiovascular somatic symptom disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disorientation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Panic attack | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immunoglobulins decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood uric acid increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Monocyte count increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Overdose | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic transfusion reaction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Epidermolysis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pericardial disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus bradycardia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aphasia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amnesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensory disturbance | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 8 (37.50%) | 2 / 2 (100.00%) |
| occurrences (all) | 0 | 4 | 3 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemolytic anaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 3 / 8 (37.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 4 / 8 (50.00%) | 2 / 2 (100.00%) |
| occurrences (all) | 1 | 9 | 5 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 8 (25.00%) | 2 / 2 (100.00%) |
| occurrences (all) | 0 | 2 | 6 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone marrow failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Ear discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Blepharitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Retinopathy hypertensive | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Cataract | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid ptosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iritis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital oedema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous detachment | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 3 (100.00%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 5 | 2 | 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 4 / 8 (50.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |

| | | | |
|---|---|---|---|
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal fissure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Lip dry | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip haematoma | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular icterus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis exfoliative generalised | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 8 | 0 |
| Skin fissures | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Skin lesion | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychoclasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neurodermatitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Purpura | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Micturition urgency | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis haemorrhagic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal impairment | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Back pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain in jaw | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle mass | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb mass | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint noise | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial cyst | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Rhinitis | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes ophthalmic | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Human herpesvirus 6 infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stenotrophomonas sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prostate infection | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection viral | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 2 / 8 (25.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 3 (33.33%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 1 / 2 (50.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 1 / 8 (12.50%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypomagnesaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlactacidaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gout | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polydipsia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 3 (0.00%) | 0 / 8 (0.00%) | 0 / 2 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Part 2, Arm D MCL: DUR 1500 mg | Part 2, Arm D DLBCL: DUR 1500 mg | Part 2 Arm D FL: DUR 1500 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 5 (100.00%) | 10 / 10 (100.00%) | 5 / 5 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |

| | | | |
|---|---|---|---|
| Cancer pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour flare | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Aortic stenosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Shock | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Asthenia | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 2 / 10 (20.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 4 | 2 | 1 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Early satiety | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 0 | 1 | 3 |
| Pyrexia | | | |
| subjects affected / exposed | 4 / 5 (80.00%) | 6 / 10 (60.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 5 | 8 | 3 |
| Discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gravitational oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nodule | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumatosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Vaginal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 10 (10.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 2 | 1 | 2 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 10 (20.00%) | 3 / 5 (60.00%) |
| occurrences (all) | 0 | 3 | 3 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngeal inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rales | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Apathy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Confusional state | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Depression | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cardiovascular somatic symptom disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disorientation | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood glucose increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunoglobulins decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 3 | 1 | 1 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood uric acid increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Monocyte count increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Contusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Overdose | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Wound | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic transfusion reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Procedural pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Epidermolysis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pericardial disease | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Sinus bradycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Aphasia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysgeusia | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 2 | 0 | 1 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Headache | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Tremor | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Amnesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensory disturbance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 10 (20.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 7 | 4 | 1 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 3 / 10 (30.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 8 | 5 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 4 / 10 (40.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 6 | 4 | 1 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone marrow failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Ear discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Eye disorders | | | |
| Blepharitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Retinopathy hypertensive | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Conjunctival oedema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid ptosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vitreous detachment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 3 | 0 | 1 |
| Constipation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 2 | 1 | 1 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Gingival pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 4 | 1 | 1 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal fissure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Dental caries | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip haematoma | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatocellular injury | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis exfoliative generalised | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pruritus | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin fissures | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychoclasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Neurodermatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Purpura | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Micturition urgency | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal impairment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle mass | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Limb mass | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint noise | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Influenza | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes ophthalmic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Human herpesvirus 6 infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stenotrophomonas sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Prostate infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection viral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 10 (20.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 1 | 2 | 2 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 10 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Hyperkalaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 2 | 1 | 1 |
| Hypokalaemia | | | |
| subjects affected / exposed | 3 / 5 (60.00%) | 2 / 10 (20.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 3 | 2 | 3 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 10 (10.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 2 | 1 | 1 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperlactacidaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gout | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polydipsia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Part 2 Arm C CLL/SLL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C DLBCL: DUR 1500 + RIT 375 + BEN 70 | Part 2 Arm C FL: DUR 1500 + RIT 375 + BEN 70 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 5 (100.00%) | 9 / 10 (90.00%) | 10 / 10 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tumour flare | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Aortic stenosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Deep vein thrombosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Shock | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 3 / 10 (30.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 3 | 1 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 3 / 10 (30.00%) | 3 / 10 (30.00%) |
| occurrences (all) | 2 | 4 | 3 |
| Early satiety | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 10 (20.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 4 / 10 (40.00%) | 3 / 10 (30.00%) |
| occurrences (all) | 1 | 5 | 3 |
| Discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gravitational oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Feeling hot | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumatosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |

| | | | |
|---|---|---|---|
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 10 (20.00%) | 4 / 10 (40.00%) |
| occurrences (all) | 1 | 3 | 4 |
| Dyspnoea | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 2 / 10 (20.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 3 | 2 | 1 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngeal inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pleural effusion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Interstitial lung disease | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rales | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Apathy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Cardiovascular somatic symptom disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disorientation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood bilirubin increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunoglobulins decreased | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| White blood cell count decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood uric acid increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Monocyte count increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Fall | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Overdose | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Allergic transfusion reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Epidermolysis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Pericardial disease | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus bradycardia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aphasia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 10 (20.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 2 | 1 |
| Tremor | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Amnesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Lethargy | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensory disturbance | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 5 / 10 (50.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 9 | 6 | 1 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 10 (20.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 4 | 1 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 3 / 10 (30.00%) | 6 / 10 (60.00%) |
| occurrences (all) | 1 | 5 | 7 |

| | | | |
|---|---|---|---|
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 6 / 10 (60.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 1 | 10 | 2 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone marrow failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Blepharitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Retinopathy hypertensive | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Conjunctival oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eyelid ptosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital oedema | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitreous haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous detachment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 2 | 2 | 3 |
| Constipation | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 1 / 10 (10.00%) | 3 / 10 (30.00%) |
| occurrences (all) | 1 | 1 | 3 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Dysphagia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 2 / 5 (40.00%) | 3 / 10 (30.00%) | 3 / 10 (30.00%) |
| occurrences (all) | 2 | 3 | 3 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 10 (20.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 10 (20.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 4 | 2 |

| | | | |
|---|---|---|---|
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal fissure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip haematoma | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Toothache | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis exfoliative generalised | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 10 (20.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 2 | 1 |
| Rash | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 2 / 10 (20.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin fissures | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Onychoclasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neurodermatitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psoriasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Purpura | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Micturition urgency | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal impairment | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Urinary tract pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Bone pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle mass | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb mass | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint noise | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial cyst | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Folliculitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 2 / 10 (20.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |

| | | | |
|---|---|---|---|
| Otitis externa | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 0 | 2 |

| | | | |
|---|---|---|---|
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes ophthalmic | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Human herpesvirus 6 infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stenotrophomonas sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prostate infection | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection viral | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Dehydration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 5 (40.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 5 (20.00%) | 3 / 10 (30.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 1 | 3 | 2 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlactacidaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gout | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polydipsia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 1 / 10 (10.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 5 (0.00%) | 0 / 10 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |

| **Non-serious adverse events** | Part 2 Arm B MCL: DUR 1500 + IBR 560 | Part 2, Arm D HL: DUR 1500 mg | Part 1 Arm C: DUR 1500 + RIT 375 + BEN 90 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 10 (100.00%) | 5 / 5 (100.00%) | 5 / 5 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour flare | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Aortic stenosis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Shock | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 5 (40.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Influenza like illness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 2 | 0 | 2 |
| Early satiety | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 5 (40.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 5 (40.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 2 | 1 |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 5 (40.00%) | 3 / 5 (60.00%) |
| occurrences (all) | 3 | 7 | 3 |
| Discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Face oedema | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gravitational oedema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Inflammation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Feeling hot | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nodule | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumatosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Penile oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 1 | 1 | 2 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Laryngeal inflammation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinus pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachypnoea | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic cough | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hiccups | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Interstitial lung disease | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngeal erythema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal obstruction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal dryness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia aspiration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract inflammation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rales | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Wheezing | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Apathy | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 5 (40.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Cardiovascular somatic symptom disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Disorientation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Panic attack | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Aspartate aminotransferase increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immunoglobulins decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 0 | 1 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood calcium decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood uric acid increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood lactate dehydrogenase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood urine present | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Heart rate irregular | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Creatinine renal clearance increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neutrophil count decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Monocyte count increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Ligament sprain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Overdose | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wound | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Allergic transfusion reaction | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye contusion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck injury | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Limb injury | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Joint injury | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Subdural haematoma | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth fracture | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Thermal burn | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Epidermolysis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pericardial disease | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus bradycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Aphasia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Migraine | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 5 (40.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Amnesia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lethargy | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Memory impairment | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sensory disturbance | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 2 / 5 (40.00%) | 3 / 5 (60.00%) |
| occurrences (all) | 4 | 2 | 4 |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 3 | 0 | 4 |
| Lymphopenia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 1 | 0 | 3 |

| | | | |
|---|---|---|---|
| Neutropenia | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 1 / 5 (20.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 6 | 1 | 3 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 1 / 5 (20.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 4 | 2 | 3 |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bone marrow failure | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ear discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye disorders | | | |

| | | | |
|---|---|---|---|
| Blepharitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Retinopathy hypertensive | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cataract | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctival oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid ptosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iritis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Vision blurred | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous detachment | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 5 / 10 (50.00%) | 3 / 5 (60.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 6 | 3 | 2 |
| Constipation | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 1 | 1 | 2 |
| Dyspepsia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 5 (20.00%) | 2 / 5 (40.00%) |
| occurrences (all) | 2 | 1 | 2 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Abdominal hernia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal fissure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal wall haematoma | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dental caries | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematemesis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip dry | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip haematoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatocellular injury | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholestasis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Ocular icterus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis exfoliative generalised | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Rash | | | |
| subjects affected / exposed | 4 / 10 (40.00%) | 2 / 5 (40.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin fissures | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin lesion | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decubitus ulcer | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis contact | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema asteatotic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onychoclasis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neurodermatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkeratosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eczema nummular | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus generalised | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Purpura | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash generalised | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Micturition urgency | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal failure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis haemorrhagic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Renal colic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Renal impairment | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 5 (40.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Intervertebral disc degeneration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Joint swelling | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Periarthritis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthritis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle mass | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Limb mass | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Joint noise | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Intervertebral disc disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal stiffness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Synovial cyst | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|---|---|---|---|
| Cystitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lung infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral fungal infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |

| | | | |
|---|---|---|---|
| Tooth infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chronic sinusitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacterial sepsis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Herpes simplex | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes ophthalmic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Hordeolum | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Human herpesvirus 6 infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pneumonia pseudomonal | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Stenotrophomonas sepsis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Prostate infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urinary tract infection viral | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 5 (40.00%) | 1 / 5 (20.00%) |
| occurrences (all) | 1 | 3 | 1 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 5 (20.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperlactacidaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gout | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polydipsia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 5 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Part 2 Arm B CLL/SLL: DUR 1500 + IBR 420 | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 10 (100.00%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tumour flare | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 2 | | |
| Hypertension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aortic stenosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Embolism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Axillary vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Subclavian vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Shock | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Embolism venous | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| Chills | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Asthenia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Influenza like illness | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| General physical health deterioration | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Fatigue | | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | | |
| occurrences (all) | 3 | | | |
| Early satiety | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Non-cardiac chest pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Mucosal inflammation | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Malaise | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pain | | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | | |
| occurrences (all) | 2 | | | |
| Oedema peripheral | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Pyrexia | | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | | |
| occurrences (all) | 8 | | | |
| Discomfort | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Face oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gravitational oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Inflammation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Feeling hot | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nodule | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumatosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Drug hypersensitivity | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immunodeficiency | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypogammaglobulinaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Reproductive system and breast disorders | | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Penile oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | |
| occurrences (all) | 5 | | |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 2 | | |
| Nasal congestion | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oropharyngeal pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Laryngeal inflammation | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hypoxia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pleural effusion | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Productive cough | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Sinus congestion | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Sinus disorder | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Sinus pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Tachypnoea | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Allergic cough | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Asthma | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Chronic obstructive pulmonary | | | | |

| | | | | |
|---|---|---|---|---|
| disease | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Dysphonia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hiccups | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Dyspnoea exertional | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Interstitial lung disease | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pleuritic pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pharyngeal erythema | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Nasal obstruction | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Nasal dryness | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Pneumonia aspiration | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Upper-airway cough syndrome | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Upper respiratory tract inflammation | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | |
|---|---|---|---|
| Rales | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wheezing | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Apathy | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Depression | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Insomnia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Cardiovascular somatic symptom disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Disorientation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Irritability | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Panic attack | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood glucose increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood creatinine increased | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 2 | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immunoglobulins decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lipase increased | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Platelet count decreased | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Weight decreased | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| White blood cell count decreased | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Amylase increased | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Blood calcium decreased | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Blood uric acid increased | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Blood lactate dehydrogenase increased | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Blood urine present | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Heart rate irregular | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Creatinine renal clearance increased | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| International normalised ratio increased | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lymphocyte count increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Monocyte count increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urine output decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Weight increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 2 | | |
| Ligament sprain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fall | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 2 | | |
| Overdose | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Wound | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Skin laceration | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Allergic transfusion reaction | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Arthropod bite | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 2 | | | |
| Eye contusion | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Humerus fracture | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Joint dislocation | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Procedural pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Neck injury | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Limb injury | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Joint injury | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Subdural haematoma | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tooth fracture | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Thermal burn | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital, familial and genetic disorders | | | |
| Epidermolysis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 3 | | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pericardial disease | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Palpitations | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 2 | | |
| Tachycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Supraventricular tachycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus bradycardia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nervous system disorders | | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dizziness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Aphasia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Migraine | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Headache | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tremor | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Amnesia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Depressed level of consciousness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---|---|---|
| Hypoaesthesia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Lethargy | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Memory impairment | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sciatica | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Sensory disturbance | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Taste disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Somnolence | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemolytic anaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neutropenia | | | |
| subjects affected / exposed | 4 / 10 (40.00%) | | |
| occurrences (all) | 14 | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | |
| occurrences (all) | 4 | | |
| Pancytopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immune thrombocytopenic purpura | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Bone marrow failure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Increased tendency to bruise | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear and labyrinth disorders | | | |
| Tinnitus | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Hypoacusis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---|---|---|
| Ear discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vertigo | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Eye disorders | | | |
| Blepharitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Retinopathy hypertensive | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dry eye | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Conjunctival haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cataract | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Conjunctival oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Angle closure glaucoma | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eyelid disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eyelid ptosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Iritis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Periorbital oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitreous haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitreous detachment | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 5 / 10 (50.00%) | | |
| occurrences (all) | 11 | | |
| Constipation | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |

| | | | | |
|---|---|---|---|---|
| Abdominal pain upper<br>subjects affected / exposed<br>occurrences (all) | 2 / 10 (20.00%)<br>2 | | | |
| Abdominal pain<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>2 | | | |
| Dyspepsia<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>2 | | | |
| Dry mouth<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1 | | | |
| Dysphagia<br>subjects affected / exposed<br>occurrences (all) | 2 / 10 (20.00%)<br>2 | | | |
| Flatulence<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1 | | | |
| Gastrointestinal haemorrhage<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Gastrooesophageal reflux disease<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1 | | | |
| Gingival pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Haemorrhoids<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Mouth ulceration<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Nausea<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1 | | | |

| | | | | |
|---|---|---|---|---|
| Rectal haemorrhage | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oral pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Stomatitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Vomiting | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Abdominal hernia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Anal fissure | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Abdominal wall haematoma | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Ascites | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Dental caries | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Eructation | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Haematemesis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Gastritis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | |
|---|---|---|---|
| Lip dry | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Oesophageal pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lip haematoma | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Toothache | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatobiliary disorders | | | |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hepatocellular injury | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 3 | | |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cholestasis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Jaundice cholestatic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ocular icterus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis exfoliative generalised | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dry skin | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Erythema | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | |
| occurrences (all) | 3 | | |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Night sweats | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pruritus | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Rash | | | |
| subjects affected / exposed | 4 / 10 (40.00%) | | |
| occurrences (all) | 4 | | |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin fissures | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | | |
|---|---|---|---|---|
| Skin lesion | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Urticaria | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Alopecia | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Decubitus ulcer | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Dermatitis | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Dermatitis contact | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Eczema asteatotic | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Onychoclasis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Neurodermatitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hyperkeratosis | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Eczema nummular | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Petechiae | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | | |
|---|---|---|---|---|
| Pruritus generalised<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Psoriasis<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Purpura<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Rash generalised<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Rash macular<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Rash pruritic<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Renal and urinary disorders<br>Acute kidney injury<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Dysuria<br>subjects affected / exposed<br>occurrences (all) | 2 / 10 (20.00%)<br>2 | | | |
| Haematuria<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Micturition urgency<br>subjects affected / exposed<br>occurrences (all) | 0 / 10 (0.00%)<br>0 | | | |
| Renal failure<br>subjects affected / exposed<br>occurrences (all) | 1 / 10 (10.00%)<br>1 | | | |
| Cystitis haemorrhagic | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Renal colic | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Renal impairment | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary tract pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Endocrine disorders | | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Thyroiditis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | |
| occurrences (all) | 5 | | |
| Back pain | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Bone pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Groin pain | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Flank pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Intervertebral disc degeneration | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Muscle discomfort | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Joint swelling | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Muscle spasms | | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | | |
| occurrences (all) | 3 | | | |
| Muscular weakness | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Musculoskeletal chest pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Musculoskeletal discomfort | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Musculoskeletal pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pain in jaw | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pain in extremity | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Myalgia | | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | | |
| occurrences (all) | 3 | | | |
| Neck pain | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Periarthritis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Arthritis | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 2 | | | |
| Muscle mass | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Limb mass | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Joint noise | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Intervertebral disc disorder | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Musculoskeletal stiffness | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Rotator cuff syndrome | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Synovial cyst | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | |
| occurrences (all) | 6 | | |
| Cystitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 2 | | |
| Cytomegalovirus infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Folliculitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Influenza | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Herpes zoster | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lip infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | | |
|---|---|---|---|---|
| Nasopharyngitis | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 2 | | | |
| Metapneumovirus infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Lung infection | | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | | |
| occurrences (all) | 4 | | | |
| Lower respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oral candidiasis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Otitis externa | | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | | |
| occurrences (all) | 2 | | | |
| Paronychia | | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | | |
| occurrences (all) | 3 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Respiratory tract infection | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 4 | | | |
| Oral fungal infection | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 2 | | | |
| Sinusitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Rhinovirus infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | | |
|---|---|---|---|---|
| Rhinitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Skin infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Tonsillitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Tooth infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Upper respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Urinary tract infection | | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | | | |
| occurrences (all) | 3 | | | |
| Viral infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Ear infection | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Conjunctivitis | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Chronic sinusitis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Bacterial sepsis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Herpes simplex | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | | |
|---|---|---|---|---|
| Herpes virus infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Herpes ophthalmic | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Eye infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hordeolum | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Enterocolitis infectious | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pharyngitis | | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | | |
| occurrences (all) | 1 | | | |
| Otitis media acute | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Otitis media | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Human herpesvirus 6 infection | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pneumonia pseudomonal | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Stenotrophomonas sepsis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | |
|---|---|---|---|
| Pseudomonas infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Prostate infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary tract infection viral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolism and nutrition disorders | | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 1 | | |
| Hypomagnesaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperlactacidaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gout | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences (all) | 4 | | |
| Polydipsia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypertriglyceridaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tumour lysis syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| occurrences (all) | 0 | | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 04 May 2017 | Addition of 2 new dose levels (ie, dose levels -2 and -3) to the Arm A dose finding part |
| 14 December 2017 | Discontinuation of Arm A to the enrollment of new participants |
| 12 September 2019 | Discontinuation of Follow-up Period, assessments and data collection |
| 22 April 2020 | Participants will move to a tablet formulation when the capsule formulation is no longer commercially available. For participants continuing on ibrutinib, scheduled clinic visits will be done according to standard of care per investigator's discretion. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

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

Study placed on full clinical hold by US FDA on 05Sep2017. Study closed for further enrollment and subjects discontinued from all treatments. Subjects followed for SPMs for 5 years after last subject was enrolled per protocol

Notes: