# Clinical trial results:
# A Phase Ib/II, Open-Label Study Evaluating the Safety and Pharmacokinetics of GDC-0199 (ABT-199) in Combination With Rituximab (R) or Obinutuzumab (G) Plus Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Patients With B-Cell Non-Hodgkin's Lymphoma (NHL) and Diffuse Large B-cell Lymphoma (DLBCL)

## Summary

| | |
|---|---|
| EudraCT number | 2013-003749-40 |
| Trial protocol | FR NL HU CZ ES AT |
| Global end of trial date | 28 June 2019 |

**Results information**

| | |
|---|---|
| Result version number | v3 (current) |
| This version publication date | 17 June 2020 |
| First version publication date | 12 July 2018 |
| Version creation reason | |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | GO27878 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02055820 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Hoffmann-La Roche |
| Sponsor organisation address | Grenzacherstrasse 124, Basel, Switzerland, CH-4070 |
| Public contact | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com |
| Scientific contact | Medical Communications, Hoffmann-La Roche, +41 616878333, global.trial_information@roche.com |
| Sponsor organisation name | F. Hoffmann-La Roche AG |
| Sponsor organisation address | Grenzacherstrasse 124, Basel, Switzerland, CH-4070 |
| Public contact | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com |
| Scientific contact | F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.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 | 28 June 2019 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 28 June 2019 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

This is a multicenter, open-label, dose-finding study of venetoclax administered orally in combination with rituximab (R) or obinutuzumab (G) and standard doses of cyclophosphamide, doxorubicin, vincristine and oral prednisone (CHOP) in participants with Non-Hodgkin's Lymphoma (NHL). The study consisted of 2 stages: a dose-finding Phase Ib stage and a Phase II expansion stage. In the Phase I portion of the study, participants were randomized to one of 2 treatment arms venetoclax in combination with R-CHOP (Arm A) and venetoclax in combination with G-CHOP (Arm B) and explored the doses of venetoclax in combination with R-CHOP and G-CHOP. For the Phase II portion of the study, the venetoclax dose for venetoclax + R-CHOP was on a non-continuous dosing schedule as determined by the Phase Ib portion of the study based on safety and tolerability observed in participants treated in the dose escalation portion of the study.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form

Background therapy: -

Evidence for comparator:

On 17 July 2016, Roche/Genentech as the sponsor of Study BO21005 (Goya study), a Phase III study that evaluated G CHOP versus R-CHOP in 1L DLBCL, informed through a press release that the primary endpoint of investigator-assessed PFS was not met. Given these results, Arm B (venetoclax + G-CHOP) was not expanded in Phase II in participants who are first-line with DLBCL

| | |
|---|---|
| Actual start date of recruitment | 17 November 2013 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy, Safety |
| Long term follow-up duration | 2 Years |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Australia: 18 |
| Country: Number of subjects enrolled | Austria: 11 |
| Country: Number of subjects enrolled | Canada: 19 |
| Country: Number of subjects enrolled | Czech Republic: 25 |
| Country: Number of subjects enrolled | Spain: 11 |

| | |
|---|---|
| Country: Number of subjects enrolled | France: 63 |
| Country: Number of subjects enrolled | Hungary: 12 |
| Country: Number of subjects enrolled | Italy: 20 |
| Country: Number of subjects enrolled | Netherlands: 8 |
| Country: Number of subjects enrolled | United States: 77 |
| Worldwide total number of subjects | 264 |
| EEA total number of subjects | 150 |

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) | 137 |
| From 65 to 84 years | 126 |
| 85 years and over | 1 |

## Subject disposition

### Recruitment

Recruitment details:

At start the trial had a randomised-controlled component, until July 2016 once the arm B (Gazyva) got closed following the publication of results of another trial. Since July 2016, the trial was single-arm, not randomised anymore, and kept including patients in only 1 arm (Arm A, rituximab).

### Pre-assignment

Screening details:

Phase I: Patients must have histologically confirmed Bcell NHL (never received RCHOP treatment), except MCL or SLL. Any relapsed/refractory patients should have received only a single previous treatment regimen Phase II: Patients must have previously untreated CD20positive DLBCL and IPI score must be 2-5.

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Venetoclax 200 mg +R-CHOP |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 200 milligram (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 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/m^2 dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.

| | |
|---|---|
| **Arm title** | Venetoclax 400 mg +R-CHOP |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 400 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 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/m^2 dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.

| | |
|---|---|
| **Arm title** | Venetoclax 600 mg +R-CHOP |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 600 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Rituximab 375 mg/m^2 dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| **Arm title** | Venetoclax 800 mg +R-CHOP |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 800 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I and II.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 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/m^2 dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

| **Arm title** | Venetoclax 800 mg +R-CHOP Phase II |
|---|---|

Arm description:

Phase II: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| 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/m^2 dose administered IV on Day 1 of every 21-day cycle up to Cycle 8.

| | |
|---|---|
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 800 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase II.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| **Arm title** | Venetoclax 200 mg +G-CHOP |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

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

Dosage and administration details:

Obinutuzumab administered by IV infusion as an absolute dose of 1000 mg on Days 1, 8, 15 of Cycle 1 and Day 1 of Cycles 2-8 (cycle length = 21 days).

| | |
|---|---|
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 200 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| **Arm title** | Venetoclax 400 mg +G-CHOP |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

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

Dosage and administration details:

Obinutuzumab administered by IV infusion as an absolute dose of 1000 mg on Days 1, 8, 15 of Cycle 1 and Day 1 of Cycles 2-8 (cycle length = 21 days).

| | |
|---|---|
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 400 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| **Arm title** | Venetoclax 600 mg +G-CHOP |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 600 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Obinutuzumab administered by IV infusion as an absolute dose of 1000 mg on Days 1, 8, 15 of Cycle 1 and Day 1 of Cycles 2-8 (cycle length = 21 days).

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| **Arm title** | Venetoclax 800 mg +G-CHOP A |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

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

Dosage and administration details:

Obinutuzumab administered by IV infusion as an absolute dose of 1000 mg on Days 1, 8, 15 of Cycle 1 and Day 1 of Cycles 2-8 (cycle length = 21 days).

| | |
|---|---|
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 800 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−10 of Cycle 1 and Days 1−10 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| **Arm title** | Venetoclax 800 mg +G-CHOP B |

Arm description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

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

Dosage and administration details:

Obinutuzumab administered by IV infusion as an absolute dose of 1000 mg on Days 1, 8, 15 of Cycle 1 and Day 1 of Cycles 2-8 (cycle length = 21 days).

| | |
|---|---|
| Investigational medicinal product name | Venetoclax |
| Investigational medicinal product code | |
| Other name | GDC-0199 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Venetoclax 800 milligrams (mg) tablets will be administered orally once daily (QD) on Days 4−8 of Cycle 1 and Days 1−5 of Cycles 2−8 during Phase I.

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

Dosage and administration details:

Cyclophosphamide 750 milligrams per square meter (mg/m^2) administered intravenously (IV) on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Doxorubicin 50 mg/m^2 administered IV on Day 1 of each 21-day cycle up to Cycle 6.

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

Dosage and administration details:

Vincristine 1.4 mg/m^2 (maximum 2 mg) administered IV on Day 1 of each 21-day cycle up to Cycle 6.

| | |
|---|---|
| Investigational medicinal product name | Prednisone |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Prednisone 100 mg per day orally on Days 1-5 of each 21-day cycle up to Cycle 6.

| **Number of subjects in period 1** | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP |
|---|---|---|---|
| Started | 7 | 3 | 8 |
| Completed | 6 | 3 | 7 |
| Not completed | 1 | 0 | 1 |
| Consent withdrawn by subject | - | - | - |
| Death | 1 | - | 1 |
| Lost to follow-up | - | - | - |

| **Number of subjects in period 1** | Venetoclax 800 mg +R-CHOP | Venetoclax 800 mg +R-CHOP Phase II | Venetoclax 200 mg +G-CHOP |
|---|---|---|---|
| Started | 6 | 208 | 7 |
| Completed | 3 | 159 | 5 |
| Not completed | 3 | 49 | 2 |
| Consent withdrawn by subject | - | 12 | 1 |
| Death | 2 | 33 | 1 |
| Lost to follow-up | 1 | 4 | - |

| **Number of subjects in period 1** | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax 800 mg +G-CHOP A |
|---|---|---|---|
| Started | 7 | 6 | 6 |
| Completed | 5 | 6 | 6 |
| Not completed | 2 | 0 | 0 |
| Consent withdrawn by subject | - | - | - |
| Death | 1 | - | - |
| Lost to follow-up | 1 | - | - |

| **Number of subjects in period 1** | Venetoclax 800 mg +G-CHOP B |
|---|---|
| Started | 6 |
| Completed | 6 |
| Not completed | 0 |

| | |
|---|---|
| Consent withdrawn by subject | - |
| Death | - |
| Lost to follow-up | - |

| Reporting groups | |
|---|---|
| Reporting group title | Venetoclax 200 mg +R-CHOP |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 400 mg +R-CHOP |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 600 mg +R-CHOP |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 800 mg +R-CHOP |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 800 mg +R-CHOP Phase II |
| Reporting group description: | |
| Phase II: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 200 mg +G-CHOP |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 400 mg +G-CHOP |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 600 mg +G-CHOP |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 800 mg +G-CHOP A |
| Reporting group description: | |
| Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor. | |
| Reporting group title | Venetoclax 800 mg +G-CHOP B |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| **Reporting group values** | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP |
|---|---|---|---|
| Number of subjects | 7 | 3 | 8 |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 3 | 2 | 7 |
| From 65-84 years | 4 | 1 | 1 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 67.0 | 61.0 | 57.0 |
| standard deviation | ± 9.2 | ± 13.1 | ± 9.5 |
| Sex: Female, Male<br>Units: Subjects | | | |
| Female | 3 | 2 | 2 |
| Male | 4 | 1 | 6 |
| Race<br>Units: Subjects | | | |
| Asian | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| Native Hawaiian or other Pacific Islande | 0 | 0 | 0 |
| White | 6 | 1 | 2 |
| Unknown | 1 | 2 | 6 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 6 | 1 | 2 |
| Not Stated | 1 | 2 | 6 |
| Unknown | 0 | 0 | 0 |

| **Reporting group values** | Venetoclax 800 mg +R-CHOP | Venetoclax 800 mg +R-CHOP Phase II | Venetoclax 200 mg +G-CHOP |
|---|---|---|---|
| Number of subjects | 6 | 208 | 7 |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 5 | 101 | 5 |
| From 65-84 years | 1 | 106 | 2 |
| 85 years and over | 0 | 1 | 0 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 56.3 | 61.4 | 52.1 |
| standard deviation | ± 11.9 | ± 12.8 | ± 16.2 |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 2 | 94 | 2 |
| Male | 4 | 114 | 5 |
| Race | | | |
| Units: Subjects | | | |
| Asian | 0 | 5 | 0 |
| Black or African American | 0 | 4 | 0 |
| Native Hawaiian or other Pacific Islande | 0 | 3 | 0 |
| White | 2 | 154 | 7 |
| Unknown | 4 | 42 | 0 |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 4 | 0 |
| Not Hispanic or Latino | 3 | 151 | 6 |
| Not Stated | 2 | 45 | 1 |
| Unknown | 1 | 8 | 0 |

| **Reporting group values** | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax 800 mg +G-CHOP A |
|---|---|---|---|
| Number of subjects | 7 | 6 | 6 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 6 | 3 | 3 |
| From 65-84 years | 1 | 3 | 3 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous | | | |
| Units: Years | | | |
| arithmetic mean | 60.9 | 66.7 | 60.5 |
| standard deviation | ± 6.3 | ± 4.2 | ± 13.7 |

| | | | |
|---|---|---|---|
| Sex: Female, Male<br>Units: Subjects | | | |
| Female | 5 | 4 | 4 |
| Male | 2 | 2 | 2 |
| Race<br>Units: Subjects | | | |
| Asian | 1 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| Native Hawaiian or other Pacific Islande | 0 | 0 | 0 |
| White | 2 | 4 | 5 |
| Unknown | 4 | 2 | 1 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 3 | 4 | 5 |
| Not Stated | 4 | 1 | 0 |
| Unknown | 0 | 1 | 1 |

| **Reporting group values** | Venetoclax 800 mg +G-CHOP B | Total | |
|---|---|---|---|
| Number of subjects | 6 | 264 | |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 2 | 137 | |
| From 65-84 years | 4 | 126 | |
| 85 years and over | 0 | 1 | |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 66.8 | | |
| standard deviation | ± 6.7 | - | |
| Sex: Female, Male<br>Units: Subjects | | | |
| Female | 2 | 120 | |
| Male | 4 | 144 | |
| Race<br>Units: Subjects | | | |
| Asian | 0 | 6 | |
| Black or African American | 0 | 4 | |
| Native Hawaiian or other Pacific Islande | 0 | 3 | |
| White | 4 | 187 | |
| Unknown | 2 | 64 | |
| Ethnicity<br>Units: Subjects | | | |

| | | | |
|---|---|---|---|
| Hispanic or Latino | 0 | 4 | |
| Not Hispanic or Latino | 6 | 187 | |
| Not Stated | 0 | 62 | |
| Unknown | 0 | 11 | |

## End points

### End points reporting groups

| Reporting group title | Venetoclax 200 mg +R-CHOP |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 400 mg +R-CHOP |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 600 mg +R-CHOP |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 800 mg +R-CHOP |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 800 mg +R-CHOP Phase II |
|---|---|

Reporting group description:

Phase II: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 200 mg +G-CHOP |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 400 mg +G-CHOP |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 600 mg +G-CHOP |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 800 mg +G-CHOP A |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax 800 mg +G-CHOP B |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Subject analysis set title | Venetoclax + R-CHOP 100 mg |
|---|---|
| Subject analysis set type | Safety analysis |

Subject analysis set description:

One participant in Venetoclax + R-CHOP 200mg arm mistakenly received only 100 mg instead of the planned 200 mg dose and was reported in a separate arm for PK outcome measures.

| Subject analysis set title | Venetoclax + G-CHOP 800 mg A+B |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

All participants who received Venetoclax + G-CHOP 800 mg.

| Subject analysis set title | Venetoclax + R-CHOP 800 mg Phase I and II |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

All participants who received Venetoclax + R-CHOP 800 mg.

| Subject analysis set title | Venetoclax PK population |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

All participants who received Venetoclax and provided at least one post-treatment PK sample.

| Subject analysis set title | Venetoclax 800 mg PK population |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

All participants in the study, who received 800 mg venetoclax and provided at least one post-treatment PK sample for whom data were available.

| Subject analysis set title | Venetoclax + R-CHOP Arm |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

All participants who received Venetoclax + R-CHOP.

| Subject analysis set title | Venetoclax + R-CHOP |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

All participants who received Venetoclax + R-CHOP.

| Subject analysis set title | Venetoclax 800 mg +R-CHOP Phase II ITT population |
|---|---|
| Subject analysis set type | Intention-to-treat |

Subject analysis set description:

All participants who were randomized into Venetoclax 800 mg +R-CHOP Phase II arm.

## Primary: Safety: Number of Participants With Dose-Limiting Toxicities (DLTs)

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

End point description:

DLTs were reported according to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 4.0 (NCI CTCAE v4.0). Decrease in B cells, lymphopenia, and leukopenia caused by lymphopenia were not considered DLTs but instead were expected outcomes of study treatment. Any Grade >/= 3 adverse event, that was attributed to having a reasonable possibility of being related to the combined administration of venetoclax plus R-CHOP or G-CHOP, that could not be attributed by the investigator to an alternative, clearly identifiable cause such as tumor progression, concurrent illness or medical condition, or concomitant medication and that occurred during the DLT observation period (start of venetoclax treatment through end of Cycle 2) was considered a DLT for dose-escalation purposes. Grade 3 or 4 neutropenia or thrombocytopenia identified on Day 1 of Cycle 2 or 3, resulting in dose delay were considered DLTs.

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

End point timeframe:

Start of venetoclax administration (Cycle 1 Day 4 or 3 days after first CHOP dose) up to end of Cycle 2 (cycle length = 21 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: No statistical analysis provided

[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: Analysis performed on specified subject analysis sets

| **End point values** | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 800 mg +R-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 3 | 8 | 6 |
| Units: Participants | 1 | 0 | 1 | 0 |

| **End point values** | Venetoclax 200 mg +G-CHOP | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax 800 mg +G-CHOP A |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 7 | 6 | 6 |
| Units: Participants | 2 | 1 | 1 | 0 |

| **End point values** | Venetoclax 800 mg +G-CHOP B | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 6 | | | |
| Units: Participants | 0 | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Previously Untreated DLBCL Participants With Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET-CT) Scan Using the Modified Lugano Classification assessed by Independent Review Committee (IRC)

| End point title | Percentage of Previously Untreated DLBCL Participants With Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET-CT) Scan Using the Modified Lugano Classification assessed by Independent Review Committee (IRC)[3] |
|---|---|

End point description:

CR was defined as follows according to modified Lugano classification for PET-CT-based response: Lymph nodes and extra-lymphatic sites with score 1, 2, or 3 with or without a residual mass on 5-point scale with 1) no uptake above background; 2) uptake </= mediastinum; 3) uptake < mediastinum but </= liver. No evidence of fluorodeoxyglucose (FDG)-uptake disease in marrow. If the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. Intent-to-treat. All participants who enrolled in the study were included in the ITT population.

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

End point timeframe:

Baseline up to end of treatment (up to approximately 6 months)

Notes:

[3] - 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: No statistical analysis provided

| **End point values** | Venetoclax 800 mg +R-CHOP Phase II ITT population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 211 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 68.2 (61.50 to 74.47) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants With CR Defined by PET/CT Scan in Previously Untreated DLBCL Coexpressing Both Bcl2 and cMyc Proteins (DE-DLBCL) Participants Assessed by IRC

| End point title | Percentage of Participants With CR Defined by PET/CT Scan in Previously Untreated DLBCL Coexpressing Both Bcl2 and cMyc Proteins (DE-DLBCL) Participants Assessed by IRC[4] |
|---|---|

End point description:

CR was defined as follows according to modified Lugano classification for PET/CT-based response: Lymph nodes and extra-lymphatic sites with score 1, 2, or 3 with or without a residual mass on 5-point scale with 1) no uptake above background; 2) uptake </= mediastinum; 3) uptake < mediastinum but </= liver. No evidence of fluorodeoxyglucose (FDG)-uptake disease in marrow. If the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Baseline up to end of treatment (up to approximately 6 months)

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: No statistical analysis provided

| **End point values** | Venetoclax 800 mg +R-CHOP Phase II ITT population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 81 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 66.7 (55.32 to 76.76) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Venetoclax Plasma PK: Area Under the Plasma Concentration-Time Curve (AUC)

| End point title | Venetoclax Plasma PK: Area Under the Plasma Concentration-Time Curve (AUC)[5] |
|---|---|

End point description:

AUC was calculated based on measurement of venetoclax concentration in plasma over time. Data are reported as hour*micrograms per milliliter (hr*mcg/mL). PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample. 99999=N/A

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

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 hours (Hr) postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

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: Analysis performed on specified subject analysis sets

| End point values | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 200 mg +G-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 3 | 8 | 7 |
| Units: hr*mcg/mL | | | | |
| arithmetic mean (standard deviation) | 2.51 (± 0.97) | 3.87 (± 2.41) | 3.70 (± 1.59) | 2.55 (± 1.13) |

| End point values | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax + R-CHOP 100 mg | Venetoclax + G-CHOP 800 mg A+B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 7 | 6 | 1 | 10 |
| Units: hr*mcg/mL | | | | |
| arithmetic mean (standard deviation) | 4.33 (± 1.31) | 5.13 (± 2.41) | 0.66 (± 9999) | 6.20 (± 1.71) |

| End point values | Venetoclax + R-CHOP 800 mg Phase I and II | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 124 | | | |
| Units: hr*mcg/mL | | | | |

| | | | | |
|---|---|---|---|---|
| arithmetic mean (standard deviation) | 4.51 (± 2.32) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Venetoclax Plasma PK: Time to Maximum Observed Plasma Concentration (Tmax)

| End point title | Venetoclax Plasma PK: Time to Maximum Observed Plasma Concentration (Tmax)[6] |
|---|---|

End point description:

Tmax was determined based on measurement of venetoclax concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample. 99999=N/A

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

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 Hr postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

Notes:

[6] - 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: Analysis performed on specified subject analysis sets

| End point values | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 200 mg +G-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 3 | 8 | 7 |
| Units: Hour | | | | |
| arithmetic mean (standard deviation) | 4.59 (± 1.08) | 6.50 (± 1.91) | 5.52 (± 2.07) | 5.72 (± 1.42) |

| End point values | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax + R-CHOP 100 mg | Venetoclax + G-CHOP 800 mg A+B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 7 | 6 | 1 | 10 |
| Units: Hour | | | | |
| arithmetic mean (standard deviation) | 6.56 (± 1.51) | 5.30 (± 2.38) | 4.0 (± 9999) | 5.79 (± 1.47) |

| End point values | Venetoclax + R-CHOP 800 mg Phase I and II | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 124 | | | |
| Units: Hour | | | | |

| | | | | |
|---|---|---|---|---|
| arithmetic mean (standard deviation) | 5.53 (± 1.55) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Venetoclax Plasma PK: Maximum Observed Plasma Concentration (Cmax)

| End point title | Venetoclax Plasma PK: Maximum Observed Plasma Concentration (Cmax)[7] |
|---|---|

End point description:

Cmax was determined based on measurement of venetoclax concentrations in plasma over time. Data are reported as micrograms per milliliter. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample. 99999=N/A

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

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 Hr postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

Notes:

[7] - 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: Analysis performed on specified subject analysis sets

| End point values | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 200 mg +G-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 3 | 8 | 7 |
| Units: Ug/ML | | | | |
| arithmetic mean (standard deviation) | 0.58 (± 0.32) | 0.92 (± 0.64) | 0.85 (± 0.33) | 0.52 (± 0.21) |

| End point values | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax + R-CHOP 100 mg | Venetoclax + G-CHOP 800 mg A+B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 7 | 6 | 1 | 10 |
| Units: Ug/ML | | | | |
| arithmetic mean (standard deviation) | 1.26 (± 0.3) | 1.0 (± 0.58) | 0.09 (± 9999) | 1.54 (± 0.37) |

| End point values | Venetoclax + R-CHOP 800 mg Phase I and II | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 124 | | | |
| Units: Ug/ML | | | | |

| | | | | |
|---|---|---|---|---|
| arithmetic mean (standard deviation) | 1.15 (± 0.48) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Venetoclax Plasma PK: Minimum Plasma Concentration (Cmin) within the Dosing Interval

| End point title | Venetoclax Plasma PK: Minimum Plasma Concentration (Cmin) within the Dosing Interval[8] |
|---|---|

End point description:

Cmin was determined based on measurement of venetoclax concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) & 2, 4, 6, 8 Hr postdose on Cycle 1 Day 4; predose (within 30 minutes) and 8 Hr postdose on Cycle 1 Day 8; predose (within 30 minutes) on Cycle 2, 3, 4 Day 10 (cycle length = 21 days)

Notes:

[8] - 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: Analysis performed on specified subject analysis sets

| End point values | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 200 mg +G-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 2 | 4 | 7 |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 0.522 (± 0.441) | 0.253 (± 0.247) | 0.387 (± 0.141) | 0.134 (± 0.107) |

| End point values | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax + R-CHOP 100 mg | Venetoclax + G-CHOP 800 mg A+B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 5 | 5 | 1 | 6 |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 0.395 (± 0.381) | 0.612 (± 0.535) | 0.0714 (± 9999) | 0.628 (± 0.395) |

| End point values | Venetoclax + R-CHOP 800 mg Phase I and II | | | |
|---|---|---|---|---|

| Subject group type | Subject analysis set | | | |
|---|---|---|---|---|
| Number of subjects analysed | 124 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 0.640 (± 0.451) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Prednisone Plasma PK: AUC

| End point title | Prednisone Plasma PK: AUC |
|---|---|

End point description:

AUC was determined based on measurement of Predisone concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) and 0.5, 1, 2, 4, 6 Hr after prednisone dose on Day 1 of Cycle 1 and 2 (cycle length = 21 days)

| **End point values** | Venetoclax PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 52 | | | |
| Units: hr*mcg/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Cycle 1, Day 1\| | 195 (± 72.8) | | | |
| Cycle 2, Day 1\| | 184 (± 81.2) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Prednisone Plasma PK: Tmax

| End point title | Prednisone Plasma PK: Tmax |
|---|---|

End point description:

Tmax was determined based on measurement of Predisone concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) and 0.5, 1, 2, 4, 6 Hr after prednisone dose on Day 1 of Cycle 1 and 2 (cycle length = 21 days)

| End point values | Venetoclax PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 54 | | | |
| Units: Hour | | | | |
| arithmetic mean (standard deviation) | | | | |
| Cycle 1, Day 1\| | 2.19 (± 1.61) | | | |
| Cycle 2, Day 1\| | 3.80 (± 2.52) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Prednisone Plasma PK: Cmax

| End point title | Prednisone Plasma PK: Cmax |
|---|---|

End point description:

Cmax was determined based on measurement of Predisone concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) and 0.5, 1, 2, 4, 6 Hr after prednisone dose on Day 1 of Cycle 1 and 2 (cycle length = 21 days)

| End point values | Venetoclax PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 54 | | | |
| Units: Ng/ML | | | | |
| arithmetic mean (standard deviation) | | | | |
| Cycle 1, Day 1\| | 49.9 (± 28.7) | | | |
| Cycle 2, Day 1\| | 43.2 (± 17.6) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Rituximab PK: Cmax

| End point title | Rituximab PK: Cmax |
|---|---|

End point description:

Cmax was determined based on measurement of Rituximab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK

sample.

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

End point timeframe:

Predose (within 30 minutes) on Day 1 of Cycles 1-8; end of infusion (infusion duration = 2-3 hours) on Cycle 1 Day 1; anytime during end of treatment (6-9 weeks after Cycle 8 Day 1) (cycle length = 21 days)

| **End point values** | Venetoclax 800 mg PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 7 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 173 (± 39.4) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Rituximab PK: Cmin within the Dosing Interval

| End point title | Rituximab PK: Cmin within the Dosing Interval |
|---|---|

End point description:

Cmin was determined based on measurement of Rituximab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) on Day 1 of Cycles 1-8; end of infusion (infusion duration = 2-3 hours) on Cycle 1 Day 1 (cycle length = 21 days)

| **End point values** | Venetoclax 800 mg PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 8 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 26.1 (± 13) | | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Obinutuzumab PK: Cmax

| End point title | Obinutuzumab PK: Cmax |
|---|---|

End point description:

Cmax was determined based on measurement of Obinutuzumab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) on Day 1 of Cycles 1-8; predose (within 30 minutes) and end of infusion (infusion duration = 3 Hr) on Day 1 of Cycles 1 and 2; anytime during end of treatment (6-9 weeks after Cycle 8 Day 1) (cycle length = 21 days)

| **End point values** | Venetoclax 800 mg PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 10 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 326 (± 76) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cyclophosphamide PK: Cmax

| End point title | Cyclophosphamide PK: Cmax |
|---|---|

End point description:

Cmax was determined based on measurement of Cyclophosphamide concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) and end of infusion (infusion duration = 30 minutes) on Day 1 of Cycles 1 and 2 (cycle length = 21 days)

| **End point values** | Venetoclax PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 36 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 32.1 (± 7.51) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Doxorubicin PK: Cmax

| End point title | Doxorubicin PK: Cmax |
|---|---|

End point description:

Cmax was determined based on measurement of Doxorubicin concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) and end of infusion (infusion duration = 15-30 minutes) on Day 1 of Cycles 1 and 2 (cycle length = 21 days)

| End point values | Venetoclax PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 24 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 1260 (± 911) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Vincristine PK: Cmax

| End point title | Vincristine PK: Cmax |
|---|---|

End point description:

Cmax was determined based on measurement of Rituximab concentrations in plasma over time. PK evaluable population: All patients who received study drug and provided at least one post-treatment PK sample.

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

End point timeframe:

Predose (within 30 minutes) and end of infusion (infusion duration = 10 minutes) on Day 1 of Cycles 1 and 2 (cycle length = 21 days)

| End point values | Venetoclax PK population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 28 | | | |
| Units: mcg/mL | | | | |
| arithmetic mean (standard deviation) | 54.0 (± 44.6) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With Objective Response Defined as Partial Response (PR) or Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET/CT) Using the Modified Lugano Classification assessed by IRC

| End point title | Percentage of Participants With Objective Response Defined as Partial Response (PR) or Complete Response (CR) Defined by Positron Emission Tomography-Computed Tomography (PET/CT) Using the Modified Lugano Classification assessed by IRC |
|---|---|

End point description:

Objective Response defined as PR (partial response) or CR (complete response) at end of treatment. CR: Lymph nodes and extra-lymphatic sites with score 1, 2 or 3 on a 5-point scale (with a higher score being a worse outcome). No evidence of fluorodeoxyglucose (FDG)-uptake disease in marrow. If the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. PR: Lymph nodes and extralymphatic sites with score of 4 or 5 on the 5-point scale with reduced uptake compared with baseline and residual mass(es) of any size. CT-based response criteria for PR must also be met. No new lesions. In bone marrow residual uptake could be higher than in normal marrow but must be reduced compared with baseline; persistent focal changes in the marrow to be considered for further evaluation with magnetic resonance imaging (MRI) or biopsy or an interval scan. OR=PR+CR

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

End point timeframe:

Baseline to end of treatment (up to approximately 6 months)

| **End point values** | Venetoclax 800 mg +R-CHOP Phase II ITT population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 211 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 81.5 (75.61 to 86.51) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants who are Alive and Without Disease Progression at Month 12

| End point title | Percentage of Participants who are Alive and Without Disease Progression at Month 12[9] |
|---|---|

End point description:

Progressive disease (PD) was determined using the modified Lugano classification criteria. For PET-CT-based PD: Score 4 (uptake moderately > liver) or 5 (uptake markedly higher than liver and/or new lesions) with an increase in intensity of uptake from baseline in target nodes and nodal lesions, new FDG-uptake foci of extranodal lesions consistent with lymphoma at interim or end-of-treatment assessment, no non-measured lesions, new FDG-uptake foci consistent with lymphoma, new or recurrent FDG-uptake foci in bone marrow. For CT-based PD: >/= 50% decrease in SPD of up to 6 target measureable nodes and extranodal sites; non-measured lesion should be absent/normal, have regressed, but not increased; no new lesions. All participants who enrolled in the study were included in the ITT population

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

End point timeframe:

Month 12

Notes:

[9] - 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: Analysis performed on specified subject analysis sets

| **End point values** | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 800 mg +R-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 3 | 8 | 6 |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 85.71 (59.79 to 100) | 100 (100 to 100) | 87.50 (64.58 to 100) | 66.67 (28.95 to 100) |

| **End point values** | Venetoclax 200 mg +G-CHOP | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP | Venetoclax 800 mg +G-CHOP A |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 7 | 6 | 6 |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 100 (100 to 100) | 75.00 (32.75 to 100) | 100 (100 to 100) | 100 (100 to 100) |

| **End point values** | Venetoclax 800 mg +G-CHOP B | Venetoclax 800 mg +R-CHOP Phase II ITT population | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 6 | 211 | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 100 (100 to 100) | 88.99 (82.65 to 92.10) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants With CR Defined by Computed Tomography (CT) Scan Using the Modified Lugano Classification

| End point title | Percentage of Participants With CR Defined by Computed Tomography (CT) Scan Using the Modified Lugano Classification |
|---|---|

End point description:

CR was defined as follows according to modified Lugano classification for CT-based response: Target nodes/nodal masses must have regressed to </= 1.5 cm in longest transverse diameter of a lesion (LDi), no extra-lymphatic sites of disease, absence of non-measured lesions, organ enlargement must have regressed to normal, no new lesions, and if the bone marrow was involved by lymphoma prior to treatment, the infiltrate must have cleared on repeat bone marrow biopsy. All participants who enrolled in the study were included in the ITT population

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

End point timeframe:

Baseline up to end of treatment (approx. 6 months)

| **End point values** | Venetoclax 800 mg +R-CHOP Phase II ITT population | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 211 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 37.4 (30.89 to 44.35) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Safety: Percentage of Participants With Adverse Events

| End point title | Safety: Percentage of Participants With Adverse Events |
|---|---|

End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events. All patients who enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP were included in the safety population.

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

End point timeframe:

Baseline up to approximately 36 months

| **End point values** | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 800 mg +R-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 3 | 8 | 6 |
| Units: Percentage of Participants | | | | |
| number (not applicable) | 100.00 | 100.00 | 100.00 | 100.00 |

| **End point values** | Venetoclax 800 mg +R-CHOP Phase II | Venetoclax 200 mg +G-CHOP | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 206 | 7 | 7 | 6 |
| Units: Percentage of Participants | | | | |

| | | | | |
|---|---|---|---|---|
| number (not applicable) | 99.0 | 100.00 | 100.00 | 100.00 |

| End point values | Venetoclax 800 mg +G-CHOP A | Venetoclax 800 mg +G-CHOP B | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 | 6 | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | 100.00 | 100.00 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Safety: Percentage of Participants Maintaining Relative Dose Intensity of CHOP Chemotherapy

| End point title | Safety: Percentage of Participants Maintaining Relative Dose Intensity of CHOP Chemotherapy |
|---|---|

End point description:

Maintenance of relative dose intensity was defined as a dose intensity of >/= 90%. All patients who enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP were included in the safety population.

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

End point timeframe:

Baseline up to Cycle 6 (cycle length = 21 days)

| End point values | Venetoclax + R-CHOP Arm | Venetoclax + R-CHOP | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 232 | 32 | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Cyclophosphamide\| | 89.5 | 77.4 | | |
| Doxorubicin\| | 88.6 | 77.4 | | |
| Vincristine\| | 86.6 | 78.1 | | |
| Prednisone\| | 87.4 | 81.3 | | |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Relative Dose Intensity of Venetoclax

| End point title | Relative Dose Intensity of Venetoclax |
|---|---|

End point description:

Dose intensity was categorized as < 80%, 80% to < 85%, 85% to < 90%, or >/= 90%. All patients who enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP were included in the safety population

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

End point timeframe:

Baseline up to Cycle 8 (cycle length = 21 days)

| **End point values** | Venetoclax 200 mg +R-CHOP | Venetoclax 400 mg +R-CHOP | Venetoclax 600 mg +R-CHOP | Venetoclax 800 mg +R-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 3 | 8 | 6 |
| Units: Percentage of Partcipants | | | | |
| number (not applicable) | | | | |
| <80%\| | 71.4 | 0.00 | 12.5 | 0.00 |
| 80-<85%\| | 0.00 | 0.00 | 12.5 | 0.00 |
| 85-<90%\| | 0.00 | 0.00 | 12.5 | 0.00 |
| >=90%\| | 28.6 | 100 | 62.5 | 100 |

| **End point values** | Venetoclax 800 mg +R-CHOP Phase II | Venetoclax 200 mg +G-CHOP | Venetoclax 400 mg +G-CHOP | Venetoclax 600 mg +G-CHOP |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 208 | 7 | 7 | 6 |
| Units: Percentage of Partcipants | | | | |
| number (not applicable) | | | | |
| <80%\| | 26.0 | 100 | 14.3 | 50.0 |
| 80-<85%\| | 3.4 | 0.00 | 14.3 | 16.7 |
| 85-<90%\| | 2.9 | 0.00 | 0.00 | 0.00 |
| >=90%\| | 67.6 | 0.00 | 71.4 | 33.3 |

| **End point values** | Venetoclax 800 mg +G-CHOP A | Venetoclax 800 mg +G-CHOP B | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6 | 6 | | |
| Units: Percentage of Partcipants | | | | |
| number (not applicable) | | | | |
| <80%\| | 83.3 | 100 | | |
| 80-<85%\| | 0.00 | 0.00 | | |
| 85-<90%\| | 16.7 | 0.00 | | |
| >=90%\| | 0.00 | 0.00 | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Baseline up to approximately 67 months.

Adverse event reporting additional description:

Safety population: All participants, who were enrolled in the study and received any amount of venetoclax or R-CHOP/G-CHOP were included in the safety population.

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

### Dictionary used

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

### Reporting groups

| | |
|---|---|
| Reporting group title | Venetoclax+R-CHOP 200 mg |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Reporting group title | Venetoclax+R-CHOP 400 mg |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Reporting group title | Venetoclax+R-CHOP 600 mg |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Reporting group title | Venetoclax+R-CHOP 800 mg |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Reporting group title | Venetoclax+R-CHOP 800 mg Phase II |

Reporting group description:

Phase II: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax (at dose determined in Phase I) + rituximab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Reporting group title | Venetoclax+G-CHOP 200 mg |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Reporting group title | Venetoclax+G-CHOP 400 mg |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| | |
|---|---|
| Reporting group title | Venetoclax+G-CHOP 600 mg |

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax+G-CHOP 800 mg A |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-10; Cycles 2-8 Days 1-10, Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| Reporting group title | Venetoclax+G-CHOP 800 mg B |
|---|---|

Reporting group description:

Phase I: Subjects received 6 cycles of CHOP and 8 cycles of venetoclax + obinutuzumab. Each cycle consisted of 21 days. In this arm venetoclax was administered as follows: Cycle 1 Days 4-8; Cycles 2-8 Days 1-5. Subjects who experienced ongoing response without excessive toxicity could receive up to eight cycles of CHOP following discussion between the investigator and the Medical Monitor.

| **Serious adverse events** | Venetoclax+R-CHOP 200 mg | Venetoclax+R-CHOP 400 mg | Venetoclax+R-CHOP 600 mg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 7 (71.43%) | 2 / 3 (66.67%) | 4 / 8 (50.00%) |
| number of deaths (all causes) | 1 | 0 | 1 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| ACUTE MYELOID LEUKAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ADENOLYMPHOMA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GLIOBLASTOMA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HISTIOCYTOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYELODYSPLASTIC SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| EMBOLISM | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| SUDDEN CARDIAC DEATH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COUGH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INTERSTITIAL LUNG DISEASE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PSYCHOTIC DISORDER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| BLOOD POTASSIUM INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| C-REACTIVE PROTEIN INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| CONTUSION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIGAMENT RUPTURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POST LUMBAR PUNCTURE SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SPINAL FRACTURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TOXICITY TO VARIOUS AGENTS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ATRIOVENTRICULAR BLOCK | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIAC ARREST | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIAC FAILURE CONGESTIVE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIOGENIC SHOCK | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIOMYOPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 8 (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 |
| LEFT VENTRICULAR FAILURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 ISCHAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SINUS TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SUPRAVENTRICULAR TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| CAROTID SINUS SYNDROME | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPILEPSY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOGLOSSAL NERVE PARESIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRESYNCOPE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TRANSIENT ISCHAEMIC ATTACK | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| AGRANULOCYTOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 8 (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 |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 5 / 5 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOLYTIC ANAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (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 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| OPTIC NEUROPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIVERTICULAR PERFORATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DUODENAL STENOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 DILATATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 PERFORATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 STENOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC ULCER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC ULCER PERFORATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ILEAL PERFORATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ILEUS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OBSTRUCTION GASTRIC | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL STENOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER GASTROINTESTINAL HAEMORRHAGE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 8 (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 |
| Hepatobiliary disorders | | | |
| BILE DUCT STONE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS ACUTE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DRUG-INDUCED LIVER INJURY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| JOINT SWELLING | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SPONDYLOLISTHESIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| ACUTE SINUSITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ATYPICAL PNEUMONIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERIAL SEPSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CLOSTRIDIUM COLITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIVERTICULITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EMPYEMA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ESCHERICHIA PYELONEPHRITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ESCHERICHIA URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTROENTERITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTROENTERITIS NOROVIRUS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HERPES SIMPLEX | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MENINGITIS VIRAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NASOPHARYNGITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OOPHORITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOCYSTIS JIROVECII INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 RESPIRATORY SYNCYTIAL VIRAL | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (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 |
| PSEUDOMONAL SEPSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 ABSCESS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RHINOVIRUS INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SIALOADENITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STAPHYLOCOCCAL SEPSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION PSEUDOMONAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (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 |
| DIABETES MELLITUS INADEQUATE CONTROL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| 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 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Venetoclax+R-CHOP 800 mg | Venetoclax+R-CHOP 800 mg Phase II | Venetoclax+G-CHOP 200 mg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 6 (50.00%) | 116 / 208 (55.77%) | 5 / 7 (71.43%) |
| number of deaths (all causes) | 2 | 33 | 1 |
| number of deaths resulting from adverse events | 0 | 3 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| ACUTE MYELOID LEUKAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| ADENOLYMPHOMA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GLIOBLASTOMA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| HISTIOCYTOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LUNG NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYELODYSPLASTIC SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| EMBOLISM | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| PYREXIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 6 / 7 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SUDDEN CARDIAC DEATH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Immune system disorders | | | |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| COUGH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOPTYSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INTERSTITIAL LUNG DISEASE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ORGANISING PNEUMONIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| PULMONARY EMBOLISM | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| Psychiatric disorders | | | |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PSYCHOTIC DISORDER | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| BLOOD POTASSIUM INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| CONTUSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIGAMENT RUPTURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POST LUMBAR PUNCTURE SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SPINAL FRACTURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |

| | | | |
|---|---|---|---|
| TOXICITY TO VARIOUS AGENTS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| ACUTE CORONARY SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 6 / 208 (2.88%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 6 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ATRIOVENTRICULAR BLOCK | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIAC ARREST | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| CARDIAC FAILURE CONGESTIVE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| CARDIOGENIC SHOCK | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| CARDIOMYOPATHY | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LEFT VENTRICULAR FAILURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| MYOCARDIAL ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| SINUS TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| SUPRAVENTRICULAR TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| CAROTID SINUS SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPILEPSY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| HYPOGLOSSAL NERVE PARESIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TRANSIENT ISCHAEMIC ATTACK | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| AGRANULOCYTOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 4 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 57 / 208 (27.40%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 3 / 3 | 85 / 89 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOLYTIC ANAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 / 6 (0.00%) | 19 / 208 (9.13%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 24 / 24 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| OPTIC NEUROPATHY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIVERTICULAR PERFORATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DUODENAL STENOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| DYSPHAGIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC DILATATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC PERFORATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| GASTRIC STENOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC ULCER | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| GASTRIC ULCER PERFORATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTROINTESTINAL PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| HAEMATEMESIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ILEAL PERFORATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ILEUS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| OBSTRUCTION GASTRIC | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL STENOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RECTAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SMALL INTESTINAL OBSTRUCTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| UPPER GASTROINTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 5 / 208 (2.40%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 4 / 5 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| BILE DUCT STONE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS ACUTE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DRUG-INDUCED LIVER INJURY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---|---|---|
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| ACUTE KIDNEY INJURY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| JOINT SWELLING | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (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 |
| SPONDYLOLISTHESIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| ACUTE SINUSITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| ATYPICAL PNEUMONIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERIAL SEPSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| CLOSTRIDIUM COLITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIVERTICULITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EMPYEMA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ESCHERICHIA PYELONEPHRITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| ESCHERICHIA URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTROENTERITIS NOROVIRUS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HERPES SIMPLEX | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 5 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (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 |
| LOWER RESPIRATORY TRACT INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LUNG INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MENINGITIS VIRAL | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OOPHORITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| PNEUMOCYSTIS JIROVECII INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 9 / 208 (4.33%) | 1 / 7 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 7 / 9 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMONIA RESPIRATORY SYNCYTIAL VIRAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PSEUDOMONAL SEPSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 3 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| RECTAL ABSCESS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| RHINOVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SEPSIS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 6 / 208 (2.88%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 5 / 6 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| SIALOADENITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| SINUSITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STAPHYLOCOCCAL SEPSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION PSEUDOMONAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |

| | | | |
|---|---|---|---|
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| DIABETES MELLITUS INADEQUATE CONTROL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (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 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Venetoclax+G-CHOP 400 mg | Venetoclax+G-CHOP 600 mg | Venetoclax+G-CHOP 800 mg A |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 3 / 6 (50.00%) | 5 / 6 (83.33%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| ACUTE MYELOID LEUKAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ADENOLYMPHOMA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GLIOBLASTOMA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HISTIOCYTOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LUNG NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MYELODYSPLASTIC SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| EMBOLISM | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| FATIGUE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFLAMMATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SUDDEN CARDIAC DEATH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COUGH | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INTERSTITIAL LUNG DISEASE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (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 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| CONFUSIONAL STATE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PSYCHOTIC DISORDER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| BLOOD POTASSIUM INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| C-REACTIVE PROTEIN INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| CONTUSION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LIGAMENT RUPTURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| POST LUMBAR PUNCTURE SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SPINAL FRACTURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TOXICITY TO VARIOUS AGENTS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ATRIOVENTRICULAR BLOCK | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIAC ARREST | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| CARDIAC FAILURE CONGESTIVE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIOGENIC SHOCK | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CARDIOMYOPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LEFT VENTRICULAR FAILURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 ISCHAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SINUS TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SUPRAVENTRICULAR TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |

| | | | |
|---|---|---|---|
| CAROTID SINUS SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EPILEPSY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOGLOSSAL NERVE PARESIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| POLYNEUROPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TRANSIENT ISCHAEMIC ATTACK | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| AGRANULOCYTOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ANAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | 2 / 7 (28.57%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HAEMOLYTIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 2 / 6 (33.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 4 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| OPTIC NEUROPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| DIARRHOEA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIVERTICULAR PERFORATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DUODENAL STENOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ENTEROCOLITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 DILATATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 PERFORATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 STENOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC ULCER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTRIC ULCER PERFORATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| 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 PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ILEAL PERFORATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ILEUS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (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 |
| NAUSEA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OBSTRUCTION GASTRIC | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OESOPHAGEAL STENOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PANCREATITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER GASTROINTESTINAL HAEMORRHAGE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| BILE DUCT STONE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CHOLECYSTITIS ACUTE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DRUG-INDUCED LIVER INJURY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| JOINT SWELLING | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SPONDYLOLISTHESIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| ACUTE SINUSITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ATYPICAL PNEUMONIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| BACTERIAL SEPSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CLOSTRIDIUM COLITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIVERTICULITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| EMPYEMA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (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 |
| ESCHERICHIA PYELONEPHRITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ESCHERICHIA URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| GASTROENTERITIS NOROVIRUS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HERPES SIMPLEX | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (14.29%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| MENINGITIS VIRAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| OOPHORITIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (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 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOCYSTIS JIROVECII INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 RESPIRATORY SYNCYTIAL VIRAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| PSEUDOMONAL SEPSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 ABSCESS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| RHINOVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (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 |
| SIALOADENITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| STAPHYLOCOCCAL SEPSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| URINARY TRACT INFECTION PSEUDOMONAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| DIABETES MELLITUS INADEQUATE CONTROL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| 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** | Venetoclax+G-CHOP 800 mg B | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 6 (83.33%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| ACUTE MYELOID LEUKAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| ADENOLYMPHOMA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| GLIOBLASTOMA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| HISTIOCYTOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| LUNG NEOPLASM MALIGNANT | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| MYELODYSPLASTIC SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| EMBOLISM | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HYPOTENSION | | | | |
| subjects affected / exposed | 0 / 6 (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 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| FATIGUE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| INFLAMMATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PYREXIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SUDDEN CARDIAC DEATH | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Immune system disorders | | | | |
| HYPOGAMMAGLOBULINAEMIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | |
|---|---|---|---|
| Respiratory, thoracic and mediastinal disorders | | | |
| CHRONIC OBSTRUCTIVE PULMONARY DISEASE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| COUGH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| DYSPNOEA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| HAEMOPTYSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| INTERSTITIAL LUNG DISEASE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| ORGANISING PNEUMONIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| PNEUMOTHORAX | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|---|---|---|---|---|
| PRODUCTIVE COUGH | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PULMONARY EMBOLISM | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Psychiatric disorders | | | | |
| CONFUSIONAL STATE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PSYCHOTIC DISORDER | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Investigations | | | | |
| BLOOD POTASSIUM INCREASED | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| C-REACTIVE PROTEIN INCREASED | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Injury, poisoning and procedural complications | | | | |
| CONTUSION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| INFUSION RELATED REACTION | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| LIGAMENT RUPTURE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| POST LUMBAR PUNCTURE SYNDROME | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SPINAL FRACTURE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| TOXICITY TO VARIOUS AGENTS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac disorders | | | | |
| ACUTE CORONARY SYNDROME | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ATRIAL FIBRILLATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ATRIOVENTRICULAR BLOCK | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CARDIAC ARREST | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CARDIAC FAILURE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CARDIAC FAILURE CONGESTIVE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CARDIOGENIC SHOCK | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CARDIOMYOPATHY | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| LEFT VENTRICULAR FAILURE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| MYOCARDIAL ISCHAEMIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SINUS TACHYCARDIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SUPRAVENTRICULAR TACHYCARDIA | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| TACHYCARDIA | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders | | | | |
| CAROTID SINUS SYNDROME | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| EPILEPSY | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HYPOGLOSSAL NERVE PARESIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| POLYNEUROPATHY | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PRESYNCOPE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SYNCOPE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| TRANSIENT ISCHAEMIC ATTACK | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| AGRANULOCYTOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| ANAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences causally related to treatment / all | 3 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| HAEMOLYTIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| NEUTROPENIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |

| | | | | |
|---|---|---|---|---|
| OPTIC NEUROPATHY | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal disorders | | | | |
| DIARRHOEA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DIVERTICULAR PERFORATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DUODENAL STENOSIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DYSPHAGIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ENTEROCOLITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTRIC DILATATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTRIC PERFORATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTRIC STENOSIS | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTRIC ULCER | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTRIC ULCER PERFORATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTROINTESTINAL PAIN | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HAEMATEMESIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ILEAL PERFORATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ILEUS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| NAUSEA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| OBSTRUCTION GASTRIC | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| OESOPHAGEAL STENOSIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PANCREATITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| RECTAL HAEMORRHAGE | | | | |
| subjects affected / exposed | 0 / 6 (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 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| STOMATITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| UPPER GASTROINTESTINAL HAEMORRHAGE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| VOMITING | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatobiliary disorders | | | | |
| BILE DUCT STONE | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CHOLECYSTITIS | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CHOLECYSTITIS ACUTE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DRUG-INDUCED LIVER INJURY | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin and subcutaneous tissue disorders | | | | |
| RASH MACULO-PAPULAR | | | | |
| subjects affected / exposed | 0 / 6 (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 | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | |
| BACK PAIN | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| JOINT SWELLING | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

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|---|---|---|---|---|
| PAIN IN EXTREMITY | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SPONDYLOLISTHESIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| ACUTE SINUSITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ATYPICAL PNEUMONIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| BACTERIAL SEPSIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| BRONCHITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CELLULITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CLOSTRIDIUM COLITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| CLOSTRIDIUM DIFFICILE INFECTION | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DEVICE RELATED INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DIVERTICULITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| EMPYEMA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ESCHERICHIA PYELONEPHRITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ESCHERICHIA URINARY TRACT INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTROENTERITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| GASTROENTERITIS NOROVIRUS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HERPES SIMPLEX | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| INFLUENZA | | | | |
| subjects affected / exposed | 0 / 6 (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 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| LUNG INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| MENINGITIS VIRAL | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| NASOPHARYNGITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| OOPHORITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ORAL CANDIDIASIS | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| ORAL HERPES | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PNEUMOCYSTIS JIROVECII INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PNEUMONIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PNEUMONIA RESPIRATORY SYNCYTIAL VIRAL | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| PSEUDOMONAL SEPSIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| RECTAL ABSCESS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| RESPIRATORY TRACT INFECTION | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| RHINOVIRUS INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SEPSIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SIALOADENITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SINUSITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| SKIN INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| STAPHYLOCOCCAL SEPSIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| UPPER RESPIRATORY TRACT INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| URINARY TRACT INFECTION | | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| URINARY TRACT INFECTION PSEUDOMONAL | | | | |
| subjects affected / exposed | 0 / 6 (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 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Metabolism and nutrition disorders | | | | |
| DECREASED APPETITE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DEHYDRATION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| DIABETES MELLITUS INADEQUATE CONTROL | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HYPERKALAEMIA | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HYPOKALAEMIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| HYPONATRAEMIA | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (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** | Venetoclax+R-CHOP 200 mg | Venetoclax+R-CHOP 400 mg | Venetoclax+R-CHOP 600 mg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 7 (100.00%) | 3 / 3 (100.00%) | 8 / 8 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SQUAMOUS CELL CARCINOMA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| SQUAMOUS CELL CARCINOMA OF SKIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| HOT FLUSH | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| THROMBOPHLEBITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 3 (33.33%) | 2 / 8 (25.00%) |
| occurrences (all) | 2 | 2 | 2 |

| | | | |
|---|---|---|---|
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CHILLS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FATIGUE | | | |
| subjects affected / exposed | 5 / 7 (71.43%) | 0 / 3 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all) | 5 | 0 | 3 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GAIT DISTURBANCE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION SITE EXTRAVASATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MALAISE | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 1 | 0 | 2 |
| NON-CARDIAC CHEST PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 2 | 0 | 2 |

| | | | |
|---|---|---|---|
| PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PYREXIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| UNEVALUABLE EVENT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| BREAST PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| TESTICULAR PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VAGINAL DISCHARGE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VULVOVAGINAL DRYNESS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| COUGH | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all) | 2 | 0 | 4 |
| DYSPNOEA | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 3 (33.33%) | 0 / 8 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |

| | | | |
|---|---|---|---|
| DYSPNOEA EXERTIONAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| EPISTAXIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HICCUPS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PLEURITIC PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| SINUS PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VOCAL CORD DYSFUNCTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| WHEEZING | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DEPRESSION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 3 |
| MOOD SWINGS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD MAGNESIUM DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD POTASSIUM INCREASED | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| COMPUTERISED TOMOGRAM THORAX ABNORMAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINE OUTPUT DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| FALL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HAND FRACTURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 2 / 3 (66.67%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 2 | 1 |
| MUSCLE STRAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| PROCEDURAL PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| THERMAL BURN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TRACHEAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Congenital, familial and genetic disorders | | | |
| ICHTHYOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Cardiac disorders | | | |
| ANGINA PECTORIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PALPITATIONS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| AGEUSIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CAROTID SINUS SYNDROME | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| COGNITIVE DISORDER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DISTURBANCE IN ATTENTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DIZZINESS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 1 | 0 | 2 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| HEADACHE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all) | 1 | 0 | 3 |
| HYPOAESTHESIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LETHARGY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MEMORY IMPAIRMENT | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| NEUROPATHY PERIPHERAL | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 3 (33.33%) | 3 / 8 (37.50%) |
| occurrences (all) | 2 | 2 | 3 |
| PARAESTHESIA | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| PERIPHERAL MOTOR NEUROPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PERIPHERAL SENSORY NEUROPATHY | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 3 (33.33%) | 2 / 8 (25.00%) |
| occurrences (all) | 3 | 1 | 2 |
| POST HERPETIC NEURALGIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| SYNCOPE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 9 | 0 | 1 |

| | | | |
|---|---|---|---|
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| HAEMOLYTIC ANAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 2 / 3 (66.67%) | 6 / 8 (75.00%) |
| occurrences (all) | 9 | 8 | 18 |
| PANCYTOPENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 1 / 3 (33.33%) | 3 / 8 (37.50%) |
| occurrences (all) | 7 | 2 | 5 |
| Ear and labyrinth disorders | | | |
| EAR PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TINNITUS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| DRY EYE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| EYE PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LACRIMATION INCREASED | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| PHOTOPHOBIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VISION BLURRED | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| VITREOUS FLOATERS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| CONSTIPATION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 2 / 3 (66.67%) | 3 / 8 (37.50%) |
| occurrences (all) | 1 | 2 | 3 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DENTAL CYST | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 2 / 3 (66.67%) | 2 / 8 (25.00%) |
| occurrences (all) | 10 | 4 | 2 |
| DRY MOUTH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| DYSPEPSIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| FLATULENCE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTRIC ULCER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROINTESTINAL DISORDER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| GINGIVAL PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HAEMORRHOIDS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MOUTH ULCERATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 2 |
| NAUSEA | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 2 / 3 (66.67%) | 1 / 8 (12.50%) |
| occurrences (all) | 3 | 4 | 1 |
| ORAL PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PROCTALGIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 3 (33.33%) | 1 / 8 (12.50%) |
| occurrences (all) | 2 | 1 | 1 |
| TOOTHACHE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Hepatobiliary disorders | | | |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| ALOPECIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ECCHYMOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| NAIL DISCOLOURATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| NIGHT SWEATS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PIGMENTATION DISORDER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| PURPURA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| SKIN HYPERPIGMENTATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| BLADDER HYPERTROPHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSURIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NOCTURIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| POLLAKIURIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| RENAL FAILURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY INCONTINENCE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY TRACT PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| BONE PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 3 (33.33%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| MUSCULAR WEAKNESS | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MYALGIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PAIN IN JAW | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| ANORECTAL INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 2 |
| CAMPYLOBACTER GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| CANDIDA INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CELLULITIS ORBITAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CLOSTRIDIUM DIFFICILE COLITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ENTEROVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| ERYSIPELAS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FURUNCLE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HERPES SIMPLEX | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HERPES ZOSTER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LUNG INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ORAL FUNGAL INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMONIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PSEUDOMONAL BACTERAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SEPSIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| SINUSITIS BACTERIAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| STAPHYLOCOCCAL INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TOOTH ABSCESS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VIRAL UPPER RESPIRATORY TRACT INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| VULVOVAGINAL CANDIDIASIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 3 (33.33%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 1 | 1 |
| DEHYDRATION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| FLUID RETENTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GOUT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HYPOCHLORAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 3 (33.33%) | 2 / 8 (25.00%) |
| occurrences (all) | 4 | 1 | 2 |

| | | | |
|---|---|---|---|
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 3 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Venetoclax+R-CHOP 800 mg | Venetoclax+R-CHOP 800 mg Phase II | Venetoclax+G-CHOP 200 mg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 6 (100.00%) | 204 / 208 (98.08%) | 7 / 7 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SQUAMOUS CELL CARCINOMA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SQUAMOUS CELL CARCINOMA OF SKIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 13 / 208 (6.25%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 15 | 1 |
| THROMBOPHLEBITIS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 3 / 208 (1.44%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 3 | 1 |
| General disorders and administration site conditions | | | |

| | | | |
|---|---|---|---|
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 33 / 208 (15.87%) | 2 / 7 (28.57%) |
| occurrences (all) | 0 | 41 | 2 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 12 / 208 (5.77%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 12 | 0 |
| CHILLS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 12 / 208 (5.77%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 15 | 0 |
| FATIGUE | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 81 / 208 (38.94%) | 5 / 7 (71.43%) |
| occurrences (all) | 4 | 104 | 7 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| GAIT DISTURBANCE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 4 | 1 |
| INFUSION SITE EXTRAVASATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 5 / 208 (2.40%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 5 | 2 |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 19 / 208 (9.13%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 28 | 1 |
| NON-CARDIAC CHEST PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |

| | | | |
|---|---|---|---|
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 23 / 208 (11.06%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 26 | 0 |
| PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 8 | 1 |
| PYREXIA | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 50 / 208 (24.04%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 68 | 0 |
| UNEVALUABLE EVENT | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Immune system disorders | | | |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Reproductive system and breast disorders | | | |
| BREAST PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TESTICULAR PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| VAGINAL DISCHARGE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VULVOVAGINAL DRYNESS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| COUGH | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 51 / 208 (24.52%) | 3 / 7 (42.86%) |
| occurrences (all) | 1 | 67 | 3 |

| | | | |
|---|---|---|---|
| DYSPNOEA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 22 / 208 (10.58%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 24 | 0 |
| DYSPNOEA EXERTIONAL | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| EPISTAXIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 3 | 1 |
| HICCUPS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 11 / 208 (5.29%) | 2 / 7 (28.57%) |
| occurrences (all) | 1 | 11 | 2 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 10 / 208 (4.81%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 13 | 1 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PLEURITIC PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 8 / 208 (3.85%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 8 | 0 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 11 / 208 (5.29%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 11 | 1 |
| SINUS PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| VOCAL CORD DYSFUNCTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| WHEEZING | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 9 / 208 (4.33%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 9 | 3 |
| DEPRESSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 14 / 208 (6.73%) | 2 / 7 (28.57%) |
| occurrences (all) | 1 | 17 | 2 |
| MOOD SWINGS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 0 | 1 |
| BLOOD MAGNESIUM DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD POTASSIUM INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COMPUTERISED TOMOGRAM THORAX ABNORMAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 2 | 1 |

| | | | |
|---|---|---|---|
| URINE OUTPUT DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 0 | 1 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 32 / 208 (15.38%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 33 | 0 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 0 | 1 |
| Injury, poisoning and procedural complications | | | |
| FALL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| HAND FRACTURE | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 44 / 208 (21.15%) | 4 / 7 (57.14%) |
| occurrences (all) | 3 | 48 | 4 |
| MUSCLE STRAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROCEDURAL PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| THERMAL BURN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| TRACHEAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |

| | | | |
|---|---|---|---|
| ICHTHYOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| ANGINA PECTORIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 8 | 1 |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| PALPITATIONS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 8 / 208 (3.85%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 8 | 0 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Nervous system disorders | | | |
| AGEUSIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 0 | 1 |
| CAROTID SINUS SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COGNITIVE DISORDER | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| DISTURBANCE IN ATTENTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| DIZZINESS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 24 / 208 (11.54%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 33 | 1 |
| DYSGEUSIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | 19 / 208 (9.13%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 19 | 1 |
| HEADACHE | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 28 / 208 (13.46%) | 3 / 7 (42.86%) |
| occurrences (all) | 1 | 31 | 5 |
| HYPOAESTHESIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 4 | 1 |
| LETHARGY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 0 | 1 |
| MEMORY IMPAIRMENT | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| NEUROPATHY PERIPHERAL | | | |
| subjects affected / exposed | 3 / 6 (50.00%) | 28 / 208 (13.46%) | 0 / 7 (0.00%) |
| occurrences (all) | 3 | 33 | 0 |
| PARAESTHESIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 18 / 208 (8.65%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 26 | 0 |
| PERIPHERAL MOTOR NEUROPATHY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| PERIPHERAL SENSORY NEUROPATHY | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 14 / 208 (6.73%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 14 | 0 |
| POST HERPETIC NEURALGIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 8 | 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| ANAEMIA | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 73 / 208 (35.10%) | 1 / 7 (14.29%) |
| occurrences (all) | 2 | 117 | 1 |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 9 / 208 (4.33%) | 0 / 7 (0.00%) |
| occurrences (all) | 3 | 10 | 0 |
| HAEMOLYTIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 23 / 208 (11.06%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 47 | 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 3 / 6 (50.00%) | 134 / 208 (64.42%) | 2 / 7 (28.57%) |
| occurrences (all) | 10 | 409 | 2 |
| PANCYTOPENIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 52 / 208 (25.00%) | 2 / 7 (28.57%) |
| occurrences (all) | 0 | 89 | 3 |
| Ear and labyrinth disorders | | | |
| EAR PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| TINNITUS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| Eye disorders | | | |
| DRY EYE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| EYE PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| LACRIMATION INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| PHOTOPHOBIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| VITREOUS FLOATERS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 14 / 208 (6.73%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 15 | 0 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 30 / 208 (14.42%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 38 | 0 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 12 | 1 |
| CONSTIPATION | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 67 / 208 (32.21%) | 6 / 7 (85.71%) |
| occurrences (all) | 2 | 78 | 7 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DENTAL CYST | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIARRHOEA | | | |
| subjects affected / exposed | 3 / 6 (50.00%) | 79 / 208 (37.98%) | 5 / 7 (71.43%) |
| occurrences (all) | 5 | 133 | 5 |

| | | | |
|---|---|---|---|
| DRY MOUTH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 5 / 208 (2.40%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 22 / 208 (10.58%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 27 | 1 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 7 / 208 (3.37%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 9 | 1 |
| FLATULENCE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| GASTRIC ULCER | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROINTESTINAL DISORDER | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 6 / 208 (2.88%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 7 | 0 |
| GINGIVAL PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| HAEMORRHOIDS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 15 / 208 (7.21%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 17 | 0 |
| MOUTH ULCERATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| NAUSEA | | | |
| subjects affected / exposed | 5 / 6 (83.33%) | 108 / 208 (51.92%) | 3 / 7 (42.86%) |
| occurrences (all) | 7 | 172 | 5 |
| ORAL PAIN | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 24 / 208 (11.54%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 29 | 0 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 2 | 1 |
| VOMITING | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 64 / 208 (30.77%) | 5 / 7 (71.43%) |
| occurrences (all) | 6 | 111 | 5 |
| Hepatobiliary disorders | | | |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 5 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| ALOPECIA | | | |
| subjects affected / exposed | 3 / 6 (50.00%) | 28 / 208 (13.46%) | 0 / 7 (0.00%) |
| occurrences (all) | 3 | 29 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 8 / 208 (3.85%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 9 | 0 |
| ECCHYMOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| NAIL DISCOLOURATION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| PIGMENTATION DISORDER | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 6 / 208 (2.88%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 8 | 0 |
| PURPURA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 9 / 208 (4.33%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 9 | 0 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 5 / 208 (2.40%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 5 | 1 |
| SKIN HYPERPIGMENTATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Renal and urinary disorders | | | |
| BLADDER HYPERTROPHY | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DYSURIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| NOCTURIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| POLLAKIURIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY INCONTINENCE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| URINARY TRACT PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 22 / 208 (10.58%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 23 | 1 |
| BACK PAIN | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | 29 / 208 (13.94%) | 0 / 7 (0.00%) |
| occurrences (all) | 2 | 34 | 0 |
| BONE PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 9 / 208 (4.33%) | 2 / 7 (28.57%) |
| occurrences (all) | 1 | 10 | 2 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 5 / 208 (2.40%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| MUSCULAR WEAKNESS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 10 / 208 (4.81%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 10 | 0 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| MYALGIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 12 / 208 (5.77%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 18 | 1 |
| PAIN IN EXTREMITY | | | |

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|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | 5 / 208 (2.40%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 5 | 0 |
| PAIN IN JAW | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| ANORECTAL INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 16 / 208 (7.69%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 18 | 0 |
| CAMPYLOBACTER GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CANDIDA INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CELLULITIS ORBITAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CLOSTRIDIUM DIFFICILE COLITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| ENTEROVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 1 | 1 |
| ERYSIPELAS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FURUNCLE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HERPES SIMPLEX | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HERPES ZOSTER | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| LUNG INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 5 | 1 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 8 / 208 (3.85%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 9 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 8 / 208 (3.85%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 9 | 0 |
| ORAL FUNGAL INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 5 / 208 (2.40%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 6 | 0 |
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | 0 / 208 (0.00%) | 1 / 7 (14.29%) |
| occurrences (all) | 1 | 0 | 1 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 5 / 208 (2.40%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| PSEUDOMONAL BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 7 | 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SINUSITIS BACTERIAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| STAPHYLOCOCCAL INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| TOOTH ABSCESS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 12 / 208 (5.77%) | 2 / 7 (28.57%) |
| occurrences (all) | 1 | 15 | 2 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 16 / 208 (7.69%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 22 | 0 |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| VIRAL UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| VULVOVAGINAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | 42 / 208 (20.19%) | 2 / 7 (28.57%) |
| occurrences (all) | 1 | 45 | 2 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 11 | 0 |
| FLUID RETENTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| GOUT | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| HYPERPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 2 | 1 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 2 / 208 (0.96%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 3 / 208 (1.44%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| HYPOCHLORAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 0 / 208 (0.00%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | 35 / 208 (16.83%) | 1 / 7 (14.29%) |
| occurrences (all) | 0 | 44 | 1 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 10 / 208 (4.81%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 12 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 4 / 208 (1.92%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 7 / 208 (3.37%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 9 | 0 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | 1 / 208 (0.48%) | 0 / 7 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| **Non-serious adverse events** | Venetoclax+G-CHOP 400 mg | Venetoclax+G-CHOP 600 mg | Venetoclax+G-CHOP 800 mg A |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 7 (100.00%) | 6 / 6 (100.00%) | 6 / 6 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SQUAMOUS CELL CARCINOMA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| SQUAMOUS CELL CARCINOMA OF SKIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 2 |
| THROMBOPHLEBITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration | | | |

| | | | |
|---|---|---|---|
| site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| CHEST PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CHILLS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FATIGUE | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 2 / 6 (33.33%) | 3 / 6 (50.00%) |
| occurrences (all) | 2 | 2 | 4 |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| GAIT DISTURBANCE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION SITE EXTRAVASATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MALAISE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 3 | 0 | 1 |
| NON-CARDIAC CHEST PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 3 / 6 (50.00%) |
| occurrences (all) | 1 | 0 | 3 |
| PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| PYREXIA | | | |
| subjects affected / exposed | 5 / 7 (71.43%) | 2 / 6 (33.33%) | 1 / 6 (16.67%) |
| occurrences (all) | 7 | 2 | 1 |
| UNEVALUABLE EVENT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| BREAST PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TESTICULAR PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VAGINAL DISCHARGE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| VULVOVAGINAL DRYNESS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|---|---|---|
| COUGH | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 6 (0.00%) | 3 / 6 (50.00%) |
| occurrences (all) | 2 | 0 | 5 |
| DYSPNOEA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| DYSPNOEA EXERTIONAL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| EPISTAXIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HICCUPS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 1 | 0 | 4 |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| PLEURITIC PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINORRHOEA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| SINUS PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| VOCAL CORD DYSFUNCTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WHEEZING | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DEPRESSION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| INSOMNIA | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| MOOD SWINGS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BLOOD MAGNESIUM DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| BLOOD POTASSIUM INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COMPUTERISED TOMOGRAM THORAX ABNORMAL | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINE OUTPUT DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 2 / 6 (33.33%) |
| occurrences (all) | 1 | 0 | 2 |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| FALL | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HAND FRACTURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 2 / 6 (33.33%) | 2 / 6 (33.33%) |
| occurrences (all) | 1 | 2 | 3 |
| MUSCLE STRAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROCEDURAL PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| THERMAL BURN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TRACHEAL OBSTRUCTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| ICHTHYOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| ANGINA PECTORIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PALPITATIONS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| TACHYCARDIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| AGEUSIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CAROTID SINUS SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COGNITIVE DISORDER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DISTURBANCE IN ATTENTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DIZZINESS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| DYSGEUSIA | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 6 (16.67%) | 2 / 6 (33.33%) |
| occurrences (all) | 3 | 1 | 2 |
| HEADACHE | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| HYPOAESTHESIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LETHARGY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MEMORY IMPAIRMENT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NEUROPATHY PERIPHERAL | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 6 (16.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 2 | 1 | 1 |
| PARAESTHESIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| PERIPHERAL MOTOR NEUROPATHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| PERIPHERAL SENSORY NEUROPATHY | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 1 | 1 |
| POST HERPETIC NEURALGIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SYNCOPE | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 5 / 6 (83.33%) |
| occurrences (all) | 1 | 4 | 8 |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 7 | 0 | 1 |
| HAEMOLYTIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| NEUTROPENIA | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 5 / 6 (83.33%) | 6 / 6 (100.00%) |
| occurrences (all) | 17 | 13 | 16 |
| PANCYTOPENIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 2 / 6 (33.33%) | 4 / 6 (66.67%) |
| occurrences (all) | 7 | 6 | 15 |
| Ear and labyrinth disorders | | | |
| EAR PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| TINNITUS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| DRY EYE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| EYE PAIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| LACRIMATION INCREASED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| PHOTOPHOBIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VITREOUS FLOATERS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 3 / 6 (50.00%) |
| occurrences (all) | 1 | 1 | 4 |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| CONSTIPATION | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 2 / 6 (33.33%) | 2 / 6 (33.33%) |
| occurrences (all) | 3 | 2 | 2 |
| DENTAL CARIES | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DENTAL CYST | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| DIARRHOEA | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 2 / 6 (33.33%) | 2 / 6 (33.33%) |
| occurrences (all) | 6 | 3 | 4 |
| DRY MOUTH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 2 | 1 |
| DYSPEPSIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| DYSPHAGIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| FLATULENCE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| GASTRIC ULCER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| GASTROINTESTINAL DISORDER | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| GINGIVAL PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HAEMORRHOIDS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| MOUTH ULCERATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NAUSEA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 7 (57.14%) | 3 / 6 (50.00%) | 5 / 6 (83.33%) |
| occurrences (all) | 7 | 4 | 10 |
| ORAL PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PROCTALGIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| STOMATITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| TOOTHACHE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VOMITING | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 0 / 6 (0.00%) | 4 / 6 (66.67%) |
| occurrences (all) | 8 | 0 | 6 |
| Hepatobiliary disorders | | | |
| CHOLELITHIASIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPERBILIRUBINAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| ALOPECIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| DRY SKIN | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| ECCHYMOSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| HYPERHIDROSIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| NAIL DISCOLOURATION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PIGMENTATION DISORDER | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 1 | 2 |
| PURPURA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 2 / 6 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| SKIN HYPERPIGMENTATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| BLADDER HYPERTROPHY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| DYSURIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HAEMATURIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| NOCTURIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| POLLAKIURIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RENAL FAILURE | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| URINARY INCONTINENCE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| URINARY TRACT PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| ARTHRALGIA | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| BACK PAIN | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| BONE PAIN | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 2 / 6 (33.33%) | 0 / 6 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| MUSCLE SPASMS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MUSCULAR WEAKNESS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 1 | 0 | 1 |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| MYALGIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PAIN IN JAW | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| ANORECTAL INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| BRONCHITIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| CAMPYLOBACTER GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| CANDIDA INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CELLULITIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CELLULITIS ORBITAL | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CLOSTRIDIUM DIFFICILE COLITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| CLOSTRIDIUM DIFFICILE INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| CONJUNCTIVITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| DEVICE RELATED INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| ENTEROVIRUS INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ERYSIPELAS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| FURUNCLE | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| HERPES SIMPLEX | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HERPES ZOSTER | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| INFLUENZA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| LUNG INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| NASOPHARYNGITIS | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| ORAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 1 | 1 |
| ORAL FUNGAL INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| ORAL HERPES | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| PNEUMONIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| PSEUDOMONAL BACTERAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| RHINITIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| SEPSIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| SINUSITIS BACTERIAL | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| SKIN INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| STAPHYLOCOCCAL INFECTION | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| TOOTH ABSCESS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 1 | 2 |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VASCULAR DEVICE INFECTION | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VIRAL UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| VULVOVAGINAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 6 (16.67%) | 2 / 6 (33.33%) |
| occurrences (all) | 2 | 1 | 2 |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| FLUID RETENTION | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 0 | 1 |
| GOUT | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| HYPERPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| HYPERURICAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOCHLORAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 6 (0.00%) | 1 / 6 (16.67%) |
| occurrences (all) | 2 | 0 | 1 |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 6 (0.00%) | 0 / 6 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 6 (16.67%) | 1 / 6 (16.67%) |
| occurrences (all) | 0 | 1 | 1 |

| **Non-serious adverse events** | Venetoclax+G-CHOP 800 mg B | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 6 / 6 (100.00%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| SQUAMOUS CELL CARCINOMA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| SQUAMOUS CELL CARCINOMA OF SKIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| Vascular disorders | | | |
| HOT FLUSH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HYPOTENSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| THROMBOPHLEBITIS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| ASTHENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| CHEST PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| CHILLS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| FATIGUE | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| FEELING ABNORMAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| GAIT DISTURBANCE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| INFLUENZA LIKE ILLNESS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| INFUSION SITE EXTRAVASATION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| MALAISE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| MUCOSAL INFLAMMATION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| NON-CARDIAC CHEST PAIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| OEDEMA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| OEDEMA PERIPHERAL | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| PAIN | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | | |
| occurrences (all) | 2 | | |
| PYREXIA | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | | |
| occurrences (all) | 2 | | |
| UNEVALUABLE EVENT | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immune system disorders | | | |
| HYPERSENSITIVITY | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| HYPOGAMMAGLOBULINAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reproductive system and breast disorders | | | |
| BREAST PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| TESTICULAR PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| VAGINAL DISCHARGE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| VULVOVAGINAL DRYNESS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| COUGH | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | | |
| occurrences (all) | 2 | | |
| DYSPNOEA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| DYSPNOEA EXERTIONAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| EPISTAXIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HICCUPS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| NASAL CONGESTION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| OROPHARYNGEAL PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PLEURAL EFFUSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PLEURITIC PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PRODUCTIVE COUGH | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| RHINORRHOEA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| SINUS PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| VOCAL CORD DYSFUNCTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| WHEEZING | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psychiatric disorders | | | |
| ANXIETY | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| DEPRESSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| INSOMNIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| MOOD SWINGS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Investigations | | | |
| ALANINE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| ASPARTATE AMINOTRANSFERASE INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| BLOOD MAGNESIUM DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| BLOOD POTASSIUM INCREASED | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| COMPUTERISED TOMOGRAM THORAX ABNORMAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| EJECTION FRACTION DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| URINE OUTPUT DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| WEIGHT DECREASED | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| WEIGHT INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| WHITE BLOOD CELL COUNT DECREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury, poisoning and procedural complications | | | |
| FALL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HAND FRACTURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| INFUSION RELATED REACTION | | | |
| subjects affected / exposed | 3 / 6 (50.00%) | | |
| occurrences (all) | 4 | | |
| MUSCLE STRAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PROCEDURAL PAIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| THERMAL BURN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| TRACHEAL OBSTRUCTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Congenital, familial and genetic disorders | | | |
| ICHTHYOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac disorders | | | |
| ANGINA PECTORIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| ATRIAL FIBRILLATION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| CARDIAC FAILURE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PALPITATIONS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| TACHYCARDIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| Nervous system disorders | | | |
| AGEUSIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| CAROTID SINUS SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| COGNITIVE DISORDER | | | |

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|---|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| DISTURBANCE IN ATTENTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| DIZZINESS | | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | | | |
| occurrences (all) | 2 | | | |
| DYSGEUSIA | | | | |
| subjects affected / exposed | 4 / 6 (66.67%) | | | |
| occurrences (all) | 4 | | | |
| HEADACHE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| HYPOAESTHESIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| LETHARGY | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| MEMORY IMPAIRMENT | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| NEUROPATHY PERIPHERAL | | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | | | |
| occurrences (all) | 3 | | | |
| PARAESTHESIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| PERIPHERAL MOTOR NEUROPATHY | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| PERIPHERAL SENSORY NEUROPATHY | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| POST HERPETIC NEURALGIA | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PRESYNCOPE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| SYNCOPE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood and lymphatic system disorders | | | |
| ANAEMIA | | | |
| subjects affected / exposed | 4 / 6 (66.67%) | | |
| occurrences (all) | 5 | | |
| FEBRILE NEUTROPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HAEMOLYTIC ANAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| LEUKOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| NEUTROPENIA | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | | |
| occurrences (all) | 10 | | |
| PANCYTOPENIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| THROMBOCYTOPENIA | | | |
| subjects affected / exposed | 2 / 6 (33.33%) | | |
| occurrences (all) | 5 | | |
| Ear and labyrinth disorders | | | |
| EAR PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| TINNITUS | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye disorders | | | |
| DRY EYE | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| EYE PAIN | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| LACRIMATION INCREASED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PHOTOPHOBIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| VISION BLURRED | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| VITREOUS FLOATERS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| ABDOMINAL DISCOMFORT | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| ABDOMINAL DISTENSION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| ABDOMINAL PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| ABDOMINAL PAIN UPPER | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| CONSTIPATION | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| DENTAL CARIES | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| DENTAL CYST | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| DIARRHOEA | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| DRY MOUTH | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| DYSPEPSIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| DYSPHAGIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| FLATULENCE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| GASTRIC ULCER | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| GASTROINTESTINAL DISORDER | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| GASTROOESOPHAGEAL REFLUX DISEASE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| GINGIVAL PAIN | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | |
|---|---|---|---|
| HAEMORRHOIDS<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| MOUTH ULCERATION<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| NAUSEA<br>subjects affected / exposed<br>occurrences (all) | 4 / 6 (66.67%)<br>6 | | |
| ORAL PAIN<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| PROCTALGIA<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| STOMATITIS<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| TOOTHACHE<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| VOMITING<br>subjects affected / exposed<br>occurrences (all) | 1 / 6 (16.67%)<br>1 | | |
| Hepatobiliary disorders<br>CHOLELITHIASIS<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| HYPERBILIRUBINAEMIA<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| Skin and subcutaneous tissue disorders<br>ALOPECIA<br>subjects affected / exposed<br>occurrences (all) | 0 / 6 (0.00%)<br>0 | | |
| DRY SKIN | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| ECCHYMOSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HYPERHIDROSIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| NAIL DISCOLOURATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| NIGHT SWEATS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PIGMENTATION DISORDER | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PRURITUS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| PURPURA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| RASH | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| RASH MACULO-PAPULAR | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| SKIN HYPERPIGMENTATION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| Renal and urinary disorders | | | |
| BLADDER HYPERTROPHY | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|---|---|---|---|
| DYSURIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| HAEMATURIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| NOCTURIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| POLLAKIURIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| RENAL FAILURE | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| URINARY INCONTINENCE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| URINARY TRACT PAIN | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Musculoskeletal and connective tissue disorders | | | | |
| ARTHRALGIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| BACK PAIN | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| BONE PAIN | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| MUSCLE SPASMS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| MUSCULAR WEAKNESS | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| MUSCULOSKELETAL CHEST PAIN | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| MYALGIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| PAIN IN EXTREMITY | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| PAIN IN JAW | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infections and infestations | | | |
| ANORECTAL INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| BRONCHITIS | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| CAMPYLOBACTER GASTROENTERITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| CANDIDA INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| CELLULITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| CELLULITIS ORBITAL | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| CLOSTRIDIUM DIFFICILE COLITIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |

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|---|---|---|---|---|
| CLOSTRIDIUM DIFFICILE INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| CONJUNCTIVITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| DEVICE RELATED INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| ENTEROVIRUS INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| ERYSIPELAS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| FURUNCLE | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| HERPES SIMPLEX | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| HERPES ZOSTER | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| INFLUENZA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| LUNG INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| NASOPHARYNGITIS | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| ORAL CANDIDIASIS | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |

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|---|---|---|---|---|
| ORAL FUNGAL INFECTION | | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | | |
| occurrences (all) | 1 | | | |
| ORAL HERPES | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| PNEUMOCYSTIS JIROVECII PNEUMONIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| PNEUMONIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| PSEUDOMONAL BACTERAEMIA | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| RHINITIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| SEPSIS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| SINUSITIS BACTERIAL | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| SKIN INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| STAPHYLOCOCCAL INFECTION | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| TOOTH ABSCESS | | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| UPPER RESPIRATORY TRACT INFECTION | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| URINARY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| VASCULAR DEVICE INFECTION | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| VIRAL UPPER RESPIRATORY TRACT INFECTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| VULVOVAGINAL CANDIDIASIS | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolism and nutrition disorders | | | |
| DECREASED APPETITE | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| DEHYDRATION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| FLUID RETENTION | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| GOUT | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| HYPERKALAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HYPERPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HYPERURICAEMIA | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HYPOCALCAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HYPOCHLORAEMIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| HYPOKALAEMIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| HYPOMAGNESAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| HYPONATRAEMIA | | | |
| subjects affected / exposed | 1 / 6 (16.67%) | | |
| occurrences (all) | 1 | | |
| HYPOPHOSPHATAEMIA | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |
| TUMOUR LYSIS SYNDROME | | | |
| subjects affected / exposed | 0 / 6 (0.00%) | | |
| occurrences (all) | 0 | | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 21 January 2014 | Changes that allow for symmetry in the treatment of patients receiving rituximab or obinutuzumab in case of hepatitis B reactivation. Changes to clarify that either antibody should be held in case of serious infection. clarification that patients with mantle cell lymphoma (MCL) and small lymphocytic lymphoma (SLL) were not eligible for the dose escalation portion of the study for safety reasons. |
| 23 May 2014 | Changes amended following identification of higher incidence of thrombocytopenia and hemorrhagic events in patients receiving obinutuzumab. Guidelines for management of patients with thrombocytopenia, especially during the first cycle have been added. |
| 01 October 2014 | An exploratory analysis of minimal residual disease has been added. Language has been added indicating the possibility of continued cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) treatment for up to eight cycles in selected patients who are tolerating therapy well and for whom it is felt by the investigator to be appropriate. Response criteria have been updated to be consistent with the 2014 Lugano Classification. Safety language has been updated. |
| 24 April 2015 | GDC-0199 dosing schedule updated. Characterization of the pharmacokinetics of the cyclophosphamide, doxorubicin and vincristine (CHO) components was deleted from the Pharmacokinetic Objectives as detailed characterization cannot be achieved with the current PK sampling scheme. |
| 07 December 2015 | An interim safety analysis has been added after 20 patients in the R-CHOP arm in the Phase II portion of the study have completed two cycles of treatment in order to confirm the safety and tolerability of the combination therapy at the venetoclax. The primary objectives of Phase II of the study have been modified to include assessment of efficacy of R-CHOP+ Venetoclax in patients with co-expression of both Bcl-2 and c-Myc. The term PET/CT will be replaced with PET-CT throughout the protocol. |
| 10 October 2016 | Venetoclax nonclinical toxicology section updated based on recent data findings. Twelve month Progression Free Survival (PFS) was added as a secondary efficacy objective. Information was added regarding the decision to not open Arm B in Phase II in DLBCL on the basis of information from the GOYA study results. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported

## Online references

http://www.ncbi.nlm.nih.gov/pubmed/30850381