# Clinical trial results:
# A Phase 1b/2 Study of BMS-813160 in Combination with Chemotherapy or Nivolumab in Patients with Advanced Solid Tumors

## Summary

| | |
|---|---|
| EudraCT number | 2017-001725-40 |
| Trial protocol | DE ES BE IT |
| Global end of trial date | 14 June 2023 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 30 June 2024 |
| First version publication date | 30 June 2024 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | CV202-103 |

**Additional study identifiers**

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

Notes:

**Sponsors**

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

Notes:

**Paediatric regulatory details**

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

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 14 June 2023 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 14 June 2023 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

To assess the safety and tolerability of BMS-813160 in combination with either FOLFIRI (Arm A), Gem + nab-paclitaxel (Arm B), or nivolumab (Arm C) in participants with advanced CRC or pancreatic cancer and to assess the pharmacodynamic effects of BMS-813160 in tumor samples

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 08 August 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Canada: 27 |
| Country: Number of subjects enrolled | United States: 252 |
| Country: Number of subjects enrolled | Belgium: 3 |
| Country: Number of subjects enrolled | Germany: 16 |
| Country: Number of subjects enrolled | Spain: 24 |
| Country: Number of subjects enrolled | Australia: 2 |
| Worldwide total number of subjects | 324 |
| EEA total number of subjects | 43 |

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) | 201 |
| From 65 to 84 years | 121 |
| 85 years and over | 2 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Participants in Cohort 1c were given the option to cross over to Cohort 8 if it's in their best interest by their treating physician. Participants will have to meet all eligibility criteria to reenter the study, undergo baseline assessment and need a 28-day washout period prior to first dose of study treatment in the new arm.

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI |

Arm description:

First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | 5-fluorouracil |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

5-fluorouracil injection

| | |
|---|---|
| Investigational medicinal product name | Irinotecan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Irinotecan injection

| | |
|---|---|
| Investigational medicinal product name | Leucovorin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Leucovorin injection

| | |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 300 mg twice a day

| **Arm title** | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI |
|---|---|

Arm description:

First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 600 mg once a day

| Investigational medicinal product name | Leucovorin |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Leucovorin injection

| Investigational medicinal product name | Irinotecan |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Irinotecan injection

| Investigational medicinal product name | 5-fluorouracil |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

5-fluorouracil injection

| **Arm title** | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB |
|---|---|

Arm description:

First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 300 mg twice a day

| Investigational medicinal product name | Nab-paclitaxel |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nab-paclitaxel 100 mg injection

| | |
|---|---|
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Gemcitabine 1000 mg injection

| | |
|---|---|
| **Arm title** | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |

Arm description:

First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE)

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 600 mg once a day

| | |
|---|---|
| Investigational medicinal product name | Nab-paclitaxel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nab-paclitaxel 100 mg injection

| | |
|---|---|
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Gemcitabine 1000 mg injection

| | |
|---|---|
| **Arm title** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO |

Arm description:

Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nivolumab 10 mg/mL

| | |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 300 mg twice a day

| **Arm title** | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO |
|---|---|

Arm description:

Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nivolumab 10 mg/mL

| Investigational medicinal product name | BMS-813160 |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet, Tablet |
| Routes of administration | Oral use, Oral use |

Dosage and administration details:

BMS-813160 600 mg once a day

| **Arm title** | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO |
|---|---|

Arm description:

Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nivolumab 10 mg/mL

| Investigational medicinal product name | BMS-813160 |
|---|---|
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 300 mg once a day

| **Arm title** | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|

Arm description:

Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nivolumab 10 mg/mL

| | |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 150 mg once a day

| | |
|---|---|
| **Arm title** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO |

Arm description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nivolumab 10 mg/mL

| | |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 300 mg twice a day

| | |
|---|---|
| **Arm title** | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO |

Arm description:

Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Nivolumab 10 mg/mL

| | |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

BMS-813160 600 mg once a day

| | |
|---|---|
| **Arm title** | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI |

Arm description:

Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer

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

| | |
|---|---|
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>BMS-813160 300 mg twice a day | |
| Investigational medicinal product name | 5-fluorouracil |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>5-fluorouracil injection | |
| Investigational medicinal product name | Leucovorin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Leucovorin injection | |
| Investigational medicinal product name | Irinotecan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Irinotecan injection | |
| **Arm title** | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
| Arm description:<br>Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer | |
| Arm type | Experimental |
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>BMS-813160 150 mg once a day | |
| Investigational medicinal product name | Leucovorin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Leucovorin injection | |
| Investigational medicinal product name | Irinotecan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

| | |
|---|---|
| Dosage and administration details:<br>Irinotecan injection | |
| Investigational medicinal product name | 5-fluorouracil |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>5-fluorouracil injection | |
| **Arm title** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI |
| Arm description:<br>Second-line treatment FOLFIRI in participants with colorectal cancer | |
| Arm type | Experimental |
| Investigational medicinal product name | 5-fluorouracil |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>5-fluorouracil injection | |
| Investigational medicinal product name | Irinotecan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Irinotecan injection | |
| Investigational medicinal product name | Leucovorin |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Leucovorin injection | |
| **Arm title** | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB |
| Arm description:<br>First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer | |
| Arm type | Experimental |
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>BMS-813160 300 mg twice a day | |
| Investigational medicinal product name | Nab-paclitaxel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

| | |
|---|---|
| Dosage and administration details:<br>Nab-paclitaxel 100 mg injection | |
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Gemcitabine 1000 mg injection | |
| **Arm title** | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO |
| Arm description:<br>First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer | |
| Arm type | Experimental |
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>BMS-813160 300 mg twice a day | |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Nivolumab 10 mg/mL | |
| Investigational medicinal product name | Nab-paclitaxel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Nab-paclitaxel 100 mg injection | |
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Gemcitabine 1000 mg injection | |
| **Arm title** | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
| Arm description:<br>First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer | |
| Arm type | Experimental |
| Investigational medicinal product name | Nab-paclitaxel |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |

| | |
|---|---|
| Dosage and administration details:<br>Nab-paclitaxel 100 mg injection | |
| Investigational medicinal product name | Gemcitabine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Gemcitabine 1000 mg injection | |
| **Arm title** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO |
| Arm description:<br>Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer | |
| Arm type | Experimental |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Nivolumab 10 mg/mL | |
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>BMS-813160 300 mg twice a day | |
| **Arm title** | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO |
| Arm description:<br>Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Arm type | Experimental |
| Investigational medicinal product name | Nivolumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intravenous use |
| Dosage and administration details:<br>Nivolumab 10 mg/mL | |
| Investigational medicinal product name | BMS-813160 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |
| Dosage and administration details:<br>BMS-813160 300 mg twice a day | |

| Number of subjects in period 1 | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB |
|---|---|---|---|
| Started | 10 | 8 | 10 |
| Cross-over | 0 | 0 | 0 |
| Completed | 0 | 0 | 0 |
| Not completed | 10 | 8 | 10 |
| Adverse event, serious fatal | 6 | 6 | 8 |
| Consent withdrawn by subject | - | - | 2 |
| Other Reasons | 2 | 2 | - |
| Lost to follow-up | 2 | - | - |

| Number of subjects in period 1 | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO |
|---|---|---|---|
| Started | 11 | 8 | 7 |
| Cross-over | 0 | 0 | 0 |
| Completed | 0 | 0 | 0 |
| Not completed | 11 | 8 | 7 |
| Adverse event, serious fatal | 8 | 6 | 6 |
| Consent withdrawn by subject | 1 | 1 | - |
| Other Reasons | 1 | - | - |
| Lost to follow-up | 1 | 1 | 1 |

| Number of subjects in period 1 | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO |
|---|---|---|---|
| Started | 7 | 11 | 1 |
| Cross-over | 0 | 0 | 0 |
| Completed | 0 | 0 | 0 |
| Not completed | 7 | 11 | 1 |
| Adverse event, serious fatal | 6 | 7 | 1 |
| Consent withdrawn by subject | 1 | - | - |
| Other Reasons | - | 2 | - |
| Lost to follow-up | - | 2 | - |

| Number of subjects in period 1 | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|
| Started | 2 | 32 | 32 |
| Cross-over | 0 | 0 | 0 |
| Completed | 0 | 0 | 0 |
| Not completed | 2 | 32 | 32 |
| Adverse event, serious fatal | 2 | 26 | 28 |

| | | | |
|---|---|---|---|
| Consent withdrawn by subject | - | - | 2 |
| Other Reasons | - | 4 | 2 |
| Lost to follow-up | - | 2 | - |

| **Number of subjects in period 1** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO |
|---|---|---|---|
| Started | 26 | 35 | 35 |
| Cross-over | 9 | 0 | 0 |
| Completed | 0 | 0 | 0 |
| Not completed | 26 | 35 | 35 |
| Adverse event, serious fatal | 17 | 33 | 34 |
| Consent withdrawn by subject | 3 | - | 1 |
| Other Reasons | 4 | - | - |
| Lost to follow-up | 2 | 2 | - |

| **Number of subjects in period 1** | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO |
|---|---|---|---|
| Started | 32 | 24 | 33 |
| Cross-over | 0 | 0 | 0 |
| Completed | 0 | 0 | 0 |
| Not completed | 32 | 24 | 33 |
| Adverse event, serious fatal | 26 | 20 | 25 |
| Consent withdrawn by subject | 5 | 2 | 2 |
| Other Reasons | 1 | - | 4 |
| Lost to follow-up | - | 2 | 2 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI |
| Reporting group description: | |
| First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer | |
| Reporting group title | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI |
| Reporting group description: | |
| First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer | |
| Reporting group title | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB |
| Reporting group description: | |
| First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer | |
| Reporting group title | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
| Reporting group description: | |
| First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE) | |
| Reporting group title | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO |
| Reporting group description: | |
| Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer | |
| Reporting group title | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO |
| Reporting group description: | |
| Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer | |
| Reporting group title | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI |
| Reporting group description: | |
| Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer | |
| Reporting group title | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
| Reporting group description: | |
| Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer | |
| Reporting group title | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI |
| Reporting group description: | |
| Second-line treatment FOLFIRI in participants with colorectal cancer | |
| Reporting group title | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB |

Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer

| Reporting group title | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO |
|---|---|

Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer

| Reporting group title | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|

Reporting group description:

First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer

| Reporting group title | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO |
|---|---|

Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

| Reporting group title | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO |
|---|---|

Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| **Reporting group values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB |
|---|---|---|---|
| Number of subjects | 10 | 8 | 10 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 4 | 5 | 5 |
| From 65-84 years | 6 | 3 | 5 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 65.6 | 53.3 | 64.1 |
| full range (min-max) | 54 to 83 | 28 to 66 | 54 to 80 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 3 | 2 | 6 |
| Male | 7 | 6 | 4 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 1 | 3 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 1 | 0 | 0 |
| White | 8 | 4 | 10 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 1 | 0 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 1 |
| Not Hispanic or Latino | 8 | 5 | 8 |
| Unknown or Not Reported | 2 | 3 | 1 |

| Reporting group values | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO |
|---|---|---|---|
| Number of subjects | 11 | 8 | 7 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 7 | 6 | 6 |
| From 65-84 years | 4 | 2 | 1 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 62.7 | 59.5 | 61.7 |
| full range (min-max) | 51 to 80 | 48 to 76 | 52 to 66 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 6 | 2 | 3 |
| Male | 5 | 6 | 4 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 1 |
| White | 11 | 8 | 5 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 1 | 0 | 0 |
| Not Hispanic or Latino | 9 | 8 | 7 |
| Unknown or Not Reported | 1 | 0 | 0 |

| Reporting group values | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO |
|---|---|---|---|
| Number of subjects | 7 | 11 | 1 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 7 | 8 | 1 |
| From 65-84 years | 0 | 3 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 45.1 | 60.5 | 61.0 |
| full range (min-max) | 33 to 57 | 42 to 77 | 61 to 61 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 3 | 3 | 1 |
| Male | 4 | 8 | 0 |

| | | | |
|---|---|---|---|
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 2 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 7 | 7 | 1 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 2 | 0 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 3 | 0 |
| Not Hispanic or Latino | 6 | 7 | 0 |
| Unknown or Not Reported | 1 | 1 | 1 |

| **Reporting group values** | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|
| Number of subjects | 2 | 32 | 32 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 2 | 25 | 21 |
| From 65-84 years | 0 | 7 | 11 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 50.0 | 55.0 | 58.9 |
| full range (min-max) | 49 to 51 | 29 to 76 | 30 to 83 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 0 | 13 | 11 |
| Male | 2 | 19 | 21 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 2 | 2 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 1 | 3 |
| White | 2 | 28 | 26 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 1 | 1 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 0 | 7 | 2 |
| Not Hispanic or Latino | 2 | 21 | 26 |
| Unknown or Not Reported | 0 | 4 | 4 |

| **Reporting group values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Number of subjects | 26 | 35 | 35 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 20 | 13 | 16 |
| From 65-84 years | 6 | 22 | 17 |
| 85 years and over | 0 | 0 | 2 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 57.9 | 65.9 | 65.3 |
| full range (min-max) | 37 to 77 | 46 to 76 | 43 to 85 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 9 | 15 | 15 |
| Male | 17 | 20 | 20 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 1 | 2 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 2 | 0 | 0 |
| White | 22 | 32 | 34 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 1 | 1 | 0 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 2 | 2 | 1 |
| Not Hispanic or Latino | 17 | 28 | 30 |
| Unknown or Not Reported | 7 | 5 | 4 |

| **Reporting group values** | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO |
|---|---|---|---|
| Number of subjects | 32 | 24 | 33 |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 15 | 11 | 29 |
| From 65-84 years | 17 | 13 | 4 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous<br>Units: Years | | | |
| arithmetic mean | 65.5 | 63.9 | 55.0 |
| full range (min-max) | 49 to 84 | 34 to 77 | 39 to 69 |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 15 | 8 | 18 |
| Male | 17 | 16 | 15 |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 1 | 1 | 1 |

| | | | |
|---|---|---|---|
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 2 | 0 | 3 |
| White | 27 | 22 | 28 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 2 | 1 | 1 |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 4 | 0 | 4 |
| Not Hispanic or Latino | 24 | 21 | 23 |
| Unknown or Not Reported | 4 | 3 | 6 |

| **Reporting group values** | Total | | |
|---|---|---|---|
| Number of subjects | 324 | | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 201 | | |
| From 65-84 years | 121 | | |
| 85 years and over | 2 | | |
| Age Continuous<br>Units: Years<br>arithmetic mean<br>full range (min-max) | <br><br><br>- | | |
| Sex: Female, Male<br>Units: Participants | | | |
| Female | 133 | | |
| Male | 191 | | |
| Race (NIH/OMB)<br>Units: Subjects | | | |
| American Indian or Alaska Native | 0 | | |
| Asian | 18 | | |
| Native Hawaiian or Other Pacific Islander | 0 | | |
| Black or African American | 13 | | |
| White | 282 | | |
| More than one race | 0 | | |
| Unknown or Not Reported | 11 | | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 27 | | |
| Not Hispanic or Latino | 250 | | |
| Unknown or Not Reported | 47 | | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI |
| Reporting group description: | |
| First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer | |
| Reporting group title | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI |
| Reporting group description: | |
| First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer | |
| Reporting group title | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB |
| Reporting group description: | |
| First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer | |
| Reporting group title | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
| Reporting group description: | |
| First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE) | |
| Reporting group title | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
| Reporting group description: | |
| Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer | |
| Reporting group title | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO |
| Reporting group description: | |
| Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer | |
| Reporting group title | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO |
| Reporting group description: | |
| Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer | |
| Reporting group title | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI |
| Reporting group description: | |
| Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer | |
| Reporting group title | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
| Reporting group description: | |
| Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer | |
| Reporting group title | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI |
| Reporting group description: | |
| Second-line treatment FOLFIRI in participants with colorectal cancer | |

| Reporting group title | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB |
|---|---|

Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer

| Reporting group title | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO |
|---|---|

Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer

| Reporting group title | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|

Reporting group description:

First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer

| Reporting group title | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO |
|---|---|

Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

| Reporting group title | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO |
|---|---|

Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer

## Primary: Number of Participants Experiencing Adverse Events (AEs)

| End point title | Number of Participants Experiencing Adverse Events (AEs)[1] |
|---|---|

End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. Adverse events are graded on a scale from 1 to 5, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization; Grade 5 events are fatal.

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

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

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: Summary statistics only were planned for this endpoint

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Participants | 10 | 8 | 10 | 11 |

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|

| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
|---|---|---|---|---|
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | 8 | 7 | 7 | 11 |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Participants | 1 | 2 | 32 | 32 |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Participants | 25 | 35 | 35 | 31 |

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | 23 | 32 | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants Experiencing Serious Adverse Events (SAEs)

| End point title | Number of Participants Experiencing Serious Adverse Events (SAEs)[2] |
|---|---|

End point description:

A Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening (defined as an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe), requires inpatient hospitalization or causes prolongation of existing hospitalization.

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

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

Notes:

[2] - 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: Summary statistics only were planned for this endpoint

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Participants | 5 | 5 | 5 | 7 |

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | 5 | 6 | 6 | 6 |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Participants | 1 | 2 | 12 | 12 |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Participants | 6 | 24 | 22 | 15 |

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | 17 | 19 | | |

## Statistical analyses

No statistical analyses for this end point

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

| End point title | Number of Participants Experiencing Dose-Limiting Toxicities (DLTs)[3] |
|---|---|

End point description:

Dose-limiting toxicities (DLTs) are severe adverse effects (AEs) that are attributed to BMS-813160 or the combination regimen and define the maximum tolerated dose of a medicine. DLTs will be defined based on the incidence, duration and grade of AEs for which no alternate cause can be identified. AEs will be evaluated according to the NCI CTCAE v4.03. The incidence of DLT(s) during the first 6 weeks of treatment in Part 1 (the DLT evaluation period) and 4 weeks for Part 2 will be used.

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

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

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: Summary statistics only were planned for this endpoint

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Participants | 0 | 0 | 2 | 2 |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | 0 | 0 | 0 | 0 |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Participants | 0 | 0 | 0 | 0 |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Participants | 0 | 0 | 1 | 0 |

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | 0 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation

| End point title | Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation[4] |
|---|---|

End point description:

An Adverse Event (AE) leading to discontinuation is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment that leads to the discontinuation of study treatment. Adverse events are graded on a scale from 1 to 5, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization; Grade 5 events are fatal.

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

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

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: Summary statistics only were planned for this endpoint

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Participants | 2 | 0 | 1 | 6 |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | 0 | 1 | 0 | 1 |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Participants | 0 | 1 | 10 | 6 |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Participants | 2 | 12 | 8 | 3 |

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | 4 | 2 | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants who Died

| End point title | Number of Participants who Died[5] |
|---|---|

End point description:

The number of participants who died within 100 days of the last dose of treatment

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

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

Notes:

[5] - 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: Summary statistics only were planned for this endpoint

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Participants | 6 | 6 | 8 | 8 |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | 6 | 6 | 6 | 7 |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Participants | 1 | 2 | 26 | 28 |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |

| | | | | |
|---|---|---|---|---|
| Units: Participants | 17 | 33 | 34 | 26 |

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | 20 | 25 | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants Experiencing Laboratory Abnormalities

| End point title | Number of Participants Experiencing Laboratory |
|---|---|

End point description:

The number of participants experiencing laboratory abnormalities in pre-specified selected parameters during the treatment period per CTCAE (Version 4). Laboratory abnormalities are graded on a scale from 1 to 5, with Grade 1 being mild and asymptomatic; Grade 2 is moderate requiring minimal, local or noninvasive intervention; Grade 3 is severe or medically significant but not immediately life-threatening; Grade 4 events are usually severe enough to require hospitalization; Grade 5 events are fatal.

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

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 3 years

Notes:

[6] - 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: Summary statistics only were planned for this endpoint

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Participants | | | | |
| ALT (U/L) - Abnormal High | 2 | 4 | 5 | 7 |
| AST (U/L) - Abnormal High | 2 | 4 | 5 | 7 |
| Total Bilirubin (UMOL/L) - Abnormal High | 2 | 4 | 5 | 2 |
| Neutrophils (Absolute) (10^9/L) - Abnormal Low | 6 | 4 | 5 | 9 |
| PLATELET COUNT (10^9/L) - Abnormal Low | 5 | 1 | 5 | 5 |

| End point values | Part 1-Arm C- | Part 1-Arm C- | Part 1-Arm C- | Part 1-Arm C- |
|---|---|---|---|---|

| | Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | | | | |
| ALT (U/L) - Abnormal High | 2 | 1 | 3 | 6 |
| AST (U/L) - Abnormal High | 3 | 3 | 5 | 5 |
| Total Bilirubin (UMOL/L) - Abnormal High | 1 | 1 | 4 | 3 |
| Neutrophils (Absolute) (10^9/L) - Abnormal Low | 2 | 1 | 1 | 2 |
| PLATELET COUNT (10^9/L) - Abnormal Low | 2 | 1 | 1 | 3 |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Participants | | | | |
| ALT (U/L) - Abnormal High | 1 | 1 | 15 | 9 |
| AST (U/L) - Abnormal High | 1 | 1 | 15 | 12 |
| Total Bilirubin (UMOL/L) - Abnormal High | 1 | 1 | 5 | 5 |
| Neutrophils (Absolute) (10^9/L) - Abnormal Low | 0 | 0 | 25 | 20 |
| PLATELET COUNT (10^9/L) - Abnormal Low | 0 | 0 | 11 | 15 |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Participants | | | | |
| ALT (U/L) - Abnormal High | 10 | 24 | 28 | 24 |
| AST (U/L) - Abnormal High | 9 | 21 | 26 | 24 |
| Total Bilirubin (UMOL/L) - Abnormal High | 2 | 8 | 7 | 5 |
| Neutrophils (Absolute) (10^9/L) - Abnormal Low | 18 | 22 | 25 | 25 |
| PLATELET COUNT (10^9/L) - Abnormal Low | 8 | 24 | 28 | 26 |

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | | | | |
| ALT (U/L) - Abnormal High | 10 | 13 | | |
| AST (U/L) - Abnormal High | 12 | 19 | | |
| Total Bilirubin (UMOL/L) - Abnormal High | 6 | 7 | | |
| Neutrophils (Absolute) (10^9/L) - Abnormal Low | 1 | 4 | | |
| PLATELET COUNT (10^9/L) - Abnormal Low | 10 | 5 | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Vital Signs

| End point title | Vital Signs[7] |
|---|---|

End point description:

Vital sign measurements at baseline and at the end of treatment. Vital signs measurements include systolic blood pressure and diastolic blood pressure.

"99999"=N/A

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

End point timeframe:

From first dose to 100 days post last dose, up to approximately 3 years

Notes:

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

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 7 | 9 | 11 |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Systolic Blood Pressure (mmHg) - Follow-up | 140.0 (± 8.5) | 124.5 (± 2.1) | 100.0 (± 99999) | 143.0 (± 34.0) |
| Systolic Blood Pressure (mmHg) - End of Treatment | 133.0 (± 99999) | 129.7 (± 6.7) | 130.2 (± 21.8) | 143.0 (± 34.0) |
| Diastolic Blood Pressure (mmHg) - Follow-up | 79.0 (± 99999) | 71.5 (± 14.8) | 59.0 (± 99999) | 99999 (± 99999) |
| Diastolic Blood Pressure (mmHg) - End of Treatment | 83.0 (± 99999) | 73.3 (± 7.2) | 75.4 (± 12.4) | 80.8 (± 17.7) |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 6 | 7 | 10 |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Systolic Blood Pressure (mmHg) - Follow-up | 140.0 (± 8.5) | 108.0 (± 99999) | 148.0 (± 99999) | 129.5 (± 29.0) |
| Systolic Blood Pressure (mmHg) - End of Treatment | 114.0 (± 15.0) | 125.0 (± 6.1) | 140.3 (± 18.0) | 124.0 (± 23.7) |
| Diastolic Blood Pressure (mmHg) - Follow-up | 85.0 (± 2.8) | 69.0 (± 99999) | 98.0 (± 99999) | 72.5 (± 4.9) |
| Diastolic Blood Pressure (mmHg) - End of Treatment | 69.6 (± 9.4) | 86.0 (± 18.2) | 89.7 (± 11.1) | 74.3 (± 11.3) |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 31 |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Systolic Blood Pressure (mmHg) - Follow-up | 99999 (± 99999) | 99999 (± 99999) | 127.9 (± 13.2) | 131.3 (± 20.6) |
| Systolic Blood Pressure (mmHg) - End of Treatment | 151.0 (± 99999) | 107.0 (± 99999) | 126.0 (± 15.9) | 113.0 (± 99999) |
| Diastolic Blood Pressure (mmHg) - Follow-up | 99999 (± 99999) | 99999 (± 99999) | 76.6 (± 14.6) | 76.1 (± 11.0) |
| Diastolic Blood Pressure (mmHg) - End of Treatment | 86.0 (± 99999) | 67.0 (± 99999) | 79.0 (± 11.5) | 74.5 (± 3.5) |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 34 | 34 | 32 |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Systolic Blood Pressure (mmHg) - Follow-up | 127.3 (± 14.4) | 130.7 (± 22.6) | 133.9 (± 15.9) | 127.1 (± 18.2) |
| Systolic Blood Pressure (mmHg) - End of Treatment | 113.0 (± 99999) | 123.2 (± 18.8) | 128.9 (± 17.8) | 118.8 (± 15.9) |
| Diastolic Blood Pressure (mmHg) - Follow-up | 78.2 (± 7.3) | 68.0 (± 9.9) | 70.2 (± 10.5) | 66.7 (± 20.1) |

| | | | | |
|---|---|---|---|---|
| Diastolic Blood Pressure (mmHg) - End of Treatment | 75.0 (± 99999) | 69.2 (± 8.2) | 74.3 (± 8.6) | 70.2 (± 8.6) |

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 23 | 31 | | |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Systolic Blood Pressure (mmHg) - Follow-up | 121.3 (± 16.3) | 128.1 (± 20.3) | | |
| Systolic Blood Pressure (mmHg) - End of Treatment | 112.6 (± 11.6) | 123.1 (± 13.6) | | |
| Diastolic Blood Pressure (mmHg) - Follow-up | 85.0 (± 99999) | 69.0 (± 2.8) | | |
| Diastolic Blood Pressure (mmHg) - End of Treatment | 68.1 (± 6.5) | 74.3 (± 9.7) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Participants with Out-of-Range Electrocardiograms (ECG)

| End point title | Number of Participants with Out-of-Range Electrocardiograms (ECG)[8] |
|---|---|

End point description:

The number of participants with ECG measurements outside of the range pre-specified in the protocol.

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

End point timeframe:

From baseline up to 100 days post last dose

Notes:

[8] - 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: Summary statistics only were planned for this endpoint

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 10 |
| Units: Participants | | | | |
| QTcF INTERVAL (MSEC) < 450 | 7 | 8 | 10 | 8 |
| QTcF INTERVAL (MSEC): 450 <= QTcF < 480 | 3 | 0 | 0 | 1 |
| 480<=QTcF<500 (MSEC) | 0 | 0 | 0 | 1 |
| QTcF>= 500 (MSEC) | 0 | 0 | 0 | 0 |
| QTcB INTERVAL (MSEC) < 450 | 4 | 7 | 8 | 5 |

| | | | | |
|---|---|---|---|---|
| 450<=QTcB<480 (MSEC) | 5 | 1 | 1 | 3 |
| 480<=QTcB<500 (MSEC) | 1 | 0 | 1 | 2 |
| QTcB>= 500 (MSEC) | 0 | 0 | 0 | 0 |

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | | | | |
| QTcF INTERVAL (MSEC) < 450 | 8 | 7 | 7 | 10 |
| QTcF INTERVAL (MSEC): 450 <= QTcF < 480 | 0 | 0 | 0 | 1 |
| 480<=QTcF<500 (MSEC) | 0 | 0 | 0 | 0 |
| QTcF>= 500 (MSEC) | 0 | 0 | 0 | 0 |
| QTcB INTERVAL (MSEC) < 450 | 7 | 3 | 3 | 7 |
| 450<=QTcB<480 (MSEC) | 1 | 4 | 3 | 2 |
| 480<=QTcB<500 (MSEC) | 0 | 0 | 1 | 2 |
| QTcB>= 500 (MSEC) | 0 | 0 | 0 | 0 |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 31 |
| Units: Participants | | | | |
| QTcF INTERVAL (MSEC) < 450 | 1 | 2 | 31 | 27 |
| QTcF INTERVAL (MSEC): 450 <= QTcF < 480 | 0 | 0 | 0 | 4 |
| 480<=QTcF<500 (MSEC) | 0 | 0 | 0 | 0 |
| QTcF>= 500 (MSEC) | 0 | 0 | 1 | 0 |
| QTcB INTERVAL (MSEC) < 450 | 1 | 2 | 20 | 21 |
| 450<=QTcB<480 (MSEC) | 0 | 0 | 11 | 7 |
| 480<=QTcB<500 (MSEC) | 0 | 0 | 0 | 3 |
| QTcB>= 500 (MSEC) | 0 | 0 | 1 | 0 |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 25 | 34 | 34 | 29 |
| Units: Participants | | | | |
| QTcF INTERVAL (MSEC) < 450 | 23 | 26 | 30 | 26 |

| | | | | |
|---|---|---|---|---|
| QTcF INTERVAL (MSEC): 450 <= QTcF < 480 | 2 | 6 | 4 | 3 |
| 480<=QTcF<500 (MSEC) | 0 | 1 | 0 | 0 |
| QTcF>= 500 (MSEC) | 0 | 1 | 0 | 0 |
| QTcB INTERVAL (MSEC) < 450 | 15 | 14 | 17 | 19 |
| 450<=QTcB<480 (MSEC) | 10 | 14 | 14 | 8 |
| 480<=QTcB<500 (MSEC) | 0 | 4 | 3 | 2 |
| QTcB>= 500 (MSEC) | 0 | 2 | 0 | 0 |

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | | | | |
| QTcF INTERVAL (MSEC) < 450 | 24 | 31 | | |
| QTcF INTERVAL (MSEC): 450 <= QTcF < 480 | 0 | 2 | | |
| 480<=QTcF<500 (MSEC) | 0 | 0 | | |
| QTcF>= 500 (MSEC) | 0 | 0 | | |
| QTcB INTERVAL (MSEC) < 450 | 21 | 15 | | |
| 450<=QTcB<480 (MSEC) | 3 | 18 | | |
| 480<=QTcB<500 (MSEC) | 0 | 0 | | |
| QTcB>= 500 (MSEC) | 0 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percent Change in Regulatory T Cells (Treg) and Tumor-Associated Macrophages (TAMs) in Tumor Samples

| End point title | Percent Change in Regulatory T Cells (Treg) and Tumor-Associated Macrophages (TAMs) in Tumor Samples[9] |
|---|---|

End point description:

The percent change in Regulatory T Cells (Treg) and Tumor-Associated Macrophages (TAMs) were taken at prespecified timepoints. Baseline is defined as the last non-missing value prior to the first dosing.

"99999"=N/A

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

End point timeframe:

From first dose up to prespecified timepoints

Notes:

[9] - 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: Summary statistics only were planned for this endpoint

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Percent change | | | | |
| median (full range (min-max)) | | | | |
| CD163 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C0D7 | 26.6 (-67 to 180) | -43.8 (-58 to -15) | -22.9 (-74 to -14) | 156.4 (-12 to 177) |
| FOXP3 - C0D14 | 26.5 (-50 to 103) | -19.8 (-78 to 53) | 60.0 (60 to 60) | -41.6 (-67 to -16) |
| FOXP3 - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |

| Units: Percent change | | | | |
|---|---|---|---|---|
| median (full range (min-max)) | | | | |
| CD163 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 13.1 (2 to 808) | -12.7 (-67 to 231) |
| CD163 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 95.4 (34 to 157) | 133.6 (0 to 286) |
| CD163 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 477.5 (334 to 621) | 22.1 (-28 to 520) |
| CD163 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 7.6 (-37 to 53) | -93 (-93 to -93) |
| CD163 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -70.2 (-91 to 107) | -17.1 (-64 to -2) |
| CD68 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 57.7 (-12 to 128) | 7.9 (-8 to 24) |
| CD68 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 294.2 (203 to 385) | 17.8 (-39 to 102) |
| CD68 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 2.9 (-26 to 185) | -26 (-26 to -26) |
| CD68 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C0D7 | 57.3 (-76 to 116) | -18.4 (-27 to -9) | -92.2 (-94 to 27) | 96.4 (14 to 152) |
| FOXP3 - C0D14 | -41 (-41 to -41) | -26.5 (-57 to 249) | 180.2 (-60 to 421) | -3.7 (-9 to 25) |
| FOXP3 - C1D1 | 34.7 (-58 to 128) | 49 (49 to 49) | 147.4 (20 to 275) | 33.0 (-51 to 338) |
| FOXP3 - C1D15 | -25.9 (-48 to -6) | 14.5 (-90 to 322) | 39.1 (4 to 74) | -33 (-33 to -33) |
| FOXP3 - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Percent change | | | | |
| median (full range (min-max)) | | | | |
| CD163 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |

| | | | | |
|---|---|---|---|---|
| CD163 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 89.8 (35 to 132) |
| CD163 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 1369 (1369 to 1369) | 99999 (99999 to 99999) |
| CD163 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -4.1 (-21 to 1072) | -58.4 (-98 to -19) |
| CD163 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -58.3 (-94 to -22) | 99999 (99999 to 99999) |
| CD68 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -4.0 (-27 to 58) |
| CD68 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 272 (272 to 272) | 99999 (99999 to 99999) |
| CD68 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 31.5 (-60 to 296) | -70.7 (-92 to -49) |
| CD68 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -26.9 (-50 to -4) | 99999 (99999 to 99999) |
| FOXP3 - C0D7 | 99999 (99999 to 99999) | 101.0 (101 to 101) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D1 | 99999 (99999 to 99999) | 31.0 (31 to 31) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -39.1 (-46 to -32) |
| FOXP3 - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -21 (-21 to -21) | 99999 (99999 to 99999) |
| FOXP3 - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -7.4 (-26 to 113) | -77.0 (-93 to -61) |
| FOXP3 - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 305.2 (-73 to 683) | 99999 (99999 to 99999) |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Percent change | | | | |
| median (full range (min-max)) | | | | |
| CD163 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD163 Positive - C1D15 | -61 (-61 to -61) | 145.7 (43 to 248) | 99999 (99999 to 99999) | 60.3 (1 to 120) |
| CD163 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |

| | | | | |
|---|---|---|---|---|
| CD163 Positive - C1D28 | 106.3 (-67 to 511) | -14.7 (-57 to 91) | 65.5 (-31 to 666) | 1.0 (-96 to 61) |
| CD163 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -41.3 (-61 to -33) |
| CD68 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D15 | 81 (81 to 81) | 162.4 (150 to 175) | 99999 (99999 to 99999) | 92.5 (20 to 165) |
| CD68 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| CD68 Positive - C1D28 | 96.2 (-50 to 1106) | -38.3 (-88 to 121) | 96.2 (-25 to 179) | -4.3 (-46 to 102) |
| CD68 Positive - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | -40.0 (-54 to -33) |
| FOXP3 - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D15 | 60 (60 to 60) | 113.6 (-1 to 228) | 99999 (99999 to 99999) | 17.0 (-39 to 73) |
| FOXP3 - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| FOXP3 - C1D28 | 12.0 (-73 to 152) | -36.0 (-77 to -5) | 99.4 (-96 to 2199) | -46.6 (-55 to 551) |
| FOXP3 - C2D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 184 (184 to 184) |

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Percent change | | | | |
| median (full range (min-max)) | | | | |
| CD163 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD163 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD163 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD163 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD163 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD163 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD163 Positive - C2D1 | 99999 (99999 to 99999) | 39.3 (-1 to 79) | | |
| CD68 Positive - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |

| | | | | |
|---|---|---|---|---|
| CD68 Positive - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD68 Positive - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD68 Positive - C1D15 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD68 Positive - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD68 Positive - C1D28 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| CD68 Positive - C2D1 | 99999 (99999 to 99999) | -66 (-66 to -66) | | |
| FOXP3 - C0D7 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| FOXP3 - C0D14 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| FOXP3 - C1D1 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| FOXP3 - C1D15 | -64 (-64 to -64) | 99999 (99999 to 99999) | | |
| FOXP3 - C1D16 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | | |
| FOXP3 - C1D28 | 216.7 (98 to 363) | -13.6 (-78 to 149) | | |
| FOXP3 - C2D1 | -2.4 (-37 to 32) | 156.2 (13 to 299) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Objective Response Rate (ORR)

| End point title | Objective Response Rate (ORR)[10] |
|---|---|

End point description:

Objective Response Rate (ORR) as determined by Investigator was defined as the number of participants with a best overall response of confirmed Complete Response (CR) or Partial Response (PR) (per RECIST 1.1 criteria) divided by the number of all treated participants. Progression is defined as at least 20% increase in the sum of diameters of target lesions and an absolute increase of at least 5 mm.

RECIST 1.1 = Response Evaluation Criteria in Solid Tumors. Complete response (CR)= Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. Partial response (PR)= At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

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

End point timeframe:

From first dose until disease progression, or the last response recorded, approximately 3 years

Notes:

[10] - 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: Summary statistics only were planned for this endpoint

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Percent of participants | | | | |
| number (confidence interval 95%) | 60.0 (26.2 to 87.8) | 25.0 (3.2 to 65.1) | 0 (0.0 to 30.8) | 18.2 (2.3 to 51.8) |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Percent of participants | | | | |
| number (confidence interval 95%) | 0 (0.0 to 36.9) | 0 (0.0 to 41.0) | 0 (0.0 to 41.0) | 0 (0.0 to 28.5) |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Percent of participants | | | | |
| number (confidence interval 95%) | 0 (0.0 to 97.5) | 0 (0.0 to 84.2) | 9.4 (2.0 to 25.0) | 9.4 (2.0 to 25.0) |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Percent of participants | | | | |
| number (confidence interval 95%) | 19.2 (6.6 to 39.4) | 22.9 (10.4 to 40.1) | 17.1 (6.6 to 33.6) | 21.9 (9.3 to 40.0) |

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|

| Subject group type | Reporting group | Reporting group | | |
|---|---|---|---|---|
| Number of subjects analysed | 24 | 24 | | |
| Units: Percent of participants | | | | |
| number (confidence interval 95%) | 0 (0.0 to 14.2) | 8.3 (1.0 to 27.0) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Duration of Response (DoR)

| End point title | Duration of Response (DoR)[11] |
|---|---|

End point description:

Duration of Response (DOR), computed for all treated participants with a best overall response (BOR) of complete response (CR) or partial response (PR), is defined as the time between the date of first response (CR or PR) and the date of first documented disease progression as determined by RECIST 1.1 or death due to any cause, whichever occurs first, ie., DOR = disease progression date/death date -first response date + 1. For participants who remain alive and have not progressed, DOR will be censored on the date of their last tumor assessment.

CR= Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. PR= At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

"99999"=N/A

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

End point timeframe:

From first response up to date of disease progression or death, whichever occurs first (up to approximately 5 years)

Notes:

[11] - 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: Summary statistics only were planned for this endpoint

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 2 | 0[12] | 2 |
| Units: Weeks | | | | |
| median (confidence interval 95%) | 159.00 (47.00 to 99999) | 99999 (16.43 to 99999) | ( to ) | 99999 (24.14 to 99999) |

Notes:

[12] - Median, lower, and upper limited not calculated due to insufficient number of events

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[13] | 0[14] | 0[15] | 0[16] |
| Units: Weeks | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | ( to ) | ( to ) |

Notes:

[13] - Median, lower, and upper limited not calculated due to insufficient number of events

[14] - Median, lower, and upper limited not calculated due to insufficient number of events

[15] - Median, lower, and upper limited not calculated due to insufficient number of events

[16] - Median, lower, and upper limited not calculated due to insufficient number of events

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[17] | 0[18] | 3 | 3 |
| Units: Weeks | | | | |
| median (confidence interval 95%) | ( to ) | ( to ) | 74.14 (32.14 to 99999) | 56.57 (40.17 to 99999) |

Notes:

[17] - Median, lower, and upper limited not calculated due to insufficient number of events

[18] - Median, lower, and upper limited not calculated due to insufficient number of events

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 7 | 6 | 7 |
| Units: Weeks | | | | |
| median (confidence interval 95%) | 36.21 (16.14 to 99999) | 32.14 (17.14 to 37.29) | 37.14 (14.14 to 99999) | 20.57 (14.29 to 31.00) |

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[19] | 2 | | |
| Units: Weeks | | | | |
| median (confidence interval 95%) | ( to ) | 99999 (41.00 to 99999) | | |

Notes:

[19] - Median, lower, and upper limited not calculated due to insufficient number of events

## Statistical analyses

No statistical analyses for this end point

## Primary: Progression Free Survival (PFS) Rate at 24 Weeks

| End point title | Progression Free Survival (PFS) Rate at 24 Weeks[20] |
|---|---|

End point description:

PFS rate is defined as the percentage of participants who were progression free at Week 24. PFS is defined as the time from first dose to the date of first objectively documented disease progression or death due to any cause, whichever occurs first. Progression is defined at least a 20% increase in the sum of diameters of target lesions and an absolute increase of at least 5 mm.

Complete response (CR)= Disappearance of all target lesions. Pathological lymph nodes must have short axis reduction to < 10 mm. Partial response (PR)= At least 30% decrease in sum of diameters of target lesions.

Participants who died w/o prior progression were considered progressed on death date. Those alive and not progressed were censored on the last tumor assessment date. Those who started subsequent therapy without reported progression were censored at last tumor assessment prior to subsequent therapy. Those without post-baseline tumor assessment and alive were censored at first dose.

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

End point timeframe:

From first dose up to Week 24

Notes:

[20] - 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: Summary statistics only were planned for this endpoint

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 4 | 5 | 6 |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 0.778 (0.3648 to 0.9393) | 99999 (99999 to 99999) | 0.556 (0.2042 to 0.8045) | 0.800 (0.4087 to 0.9459) |

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[21] | 0[22] | 0[23] | 1 |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | ( to ) | ( to ) | ( to ) | 99999 (99999 to 99999) |

Notes:

[21] - Not calculated due to insufficient number of events

[22] - Not calculated due to insufficient number of events

[23] - Not calculated due to insufficient number of events

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[24] | 0[25] | 7 | 14 |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | ( to ) | ( to ) | 0.357 (0.1699 to 0.5490) | 0.536 (0.3372 to 0.6996) |

Notes:

[24] - Not calculated due to insufficient number of events

[25] - Not calculated due to insufficient number of events

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 13 | 17 | 21 | 13 |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 0.691 (0.4361 to 0.8478) | 0.535 (0.3512 to 0.6888) | 0.636 (0.4495 to 0.7746) | 0.467 (0.2779 to 0.6358) |

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[26] | 3 | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | ( to ) | 99999 (99999 to 99999) | | |

Notes:

[26] - Not calculated due to insufficient number of events

### Statistical analyses

No statistical analyses for this end point

### Secondary: Maximim Concentration (Cmax)

| End point title | Maximim Concentration (Cmax) |
|---|---|

End point description:

Cmax is defined as the maximum plasma concentration of the analytes at the prespecified timepoints.

"99999"=N/A

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

End point timeframe:

From first dose up to the prespecified timepoints, C0D1, C0D14, AND C2D1

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 7 | 10 | 10 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 620.4 (± 250.60) | 2204.1 (± 961.90) | 828.4 (± 458.03) | 2419.0 (± 1203.53) |
| C0D1 - BMS-939429 | 172.23 (± 103.837) | 435.6 (± 284.14) | 207.63 (± 142.559) | 545.7 (± 218.89) |

| | | | | |
|---|---|---|---|---|
| C0D14 - BMS-813160 | 927.1 (± 513.88) | 4152.5 (± 2010.23) | 1060.3 (± 830.04) | 3274.0 (± 884.15) |
| C0D14 - BMS-939429 | 317.90 (± 290.209) | 658.3 (± 143.17) | 409.63 (± 382.471) | 792.2 (± 503.92) |
| C2D1 - BMS-813160 | 1153.1 (± 617.97) | 3280.0 (± 777.82) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-939429 | 254.1 (± 140.73) | 571.0 (± 376.42) | 99999 (± 99999) | 99999 (± 99999) |

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 6 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 486.3 (± 137.69) | 1896.3 (± 1421.89) | 1179.1 (± 605.50) | 276.28 (± 141.915) |
| C0D1 - BMS-939429 | 92.33 (± 50.015) | 539.1 (± 465.93) | 237.63 (± 188.286) | 54.82 (± 23.716) |
| C0D14 - BMS-813160 | 701.5 (± 284.59) | 1793.5 (± 1607.25) | 653.3 (± 298.08) | 80.00 (± 19.408) |
| C0D14 - BMS-939429 | 183.08 (± 190.050) | 326.0 (± 241.83) | 165.83 (± 92.914) | 25.307 (± 16.6021) |
| C2D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-939429 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 18 | 15 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 1580.0 (± 99999) | 807.0 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C0D1 - BMS-939429 | 504.0 (± 99999) | 72.50 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C0D14 - BMS-813160 | 1370.0 (± 99999) | 1680.0 (± 961.67) | 99999 (± 99999) | 99999 (± 99999) |
| C0D14 - BMS-939429 | 498.0 (± 99999) | 265.40 (± 235.608) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 903.9 (± 578.56) | 357.55 (± 264.384) |
| C2D1 - BMS-939429 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[27] | 20 | 0[28] | 0[29] |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | 99999 (± 99999) | () | () |
| C0D1 - BMS-939429 | () | 99999 (± 99999) | () | () |
| C0D14 - BMS-813160 | () | 99999 (± 99999) | () | () |
| C0D14 - BMS-939429 | () | 99999 (± 99999) | () | () |
| C2D1 - BMS-813160 | () | 796.2 (± 472.48) | () | () |
| C2D1 - BMS-939429 | () | 99999 (± 99999) | () | () |

Notes:

[27] - Cmax not calculated because there was an insufficient number of participants with evaluable data

[28] - Cmax not calculated because there was an insufficient number of participants with evaluable data

[29] - Cmax not calculated because there was an insufficient number of participants with evaluable data

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[30] | 0[31] | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | () | | |
| C0D1 - BMS-939429 | () | () | | |
| C0D14 - BMS-813160 | () | () | | |
| C0D14 - BMS-939429 | () | () | | |
| C2D1 - BMS-813160 | () | () | | |
| C2D1 - BMS-939429 | () | () | | |

Notes:

[30] - Cmax not calculated because there was an insufficient number of participants with evaluable data

[31] - Cmax not calculated because there was an insufficient number of participants with evaluable data

### Statistical analyses

No statistical analyses for this end point

## Secondary: Time to Maximum Concentration (Tmax)

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

End point description:

Tmax is defined as the time in hours of the maximum observed plasma concentration

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

End point timeframe:

From first dose up to the prespecified timpoints, C0D1, C0D14, AND C2D1

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 7 | 10 | 10 |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| C0D1 - BMS-813160 | 2.000 (0.50 to 4.00) | 0.500 (0.47 to 4.00) | 3.017 (2.00 to 4.02) | 2.492 (0.73 to 5.98) |
| C0D1 - BMS-939429 | 3.500 (0.50 to 6.25) | 1.000 (0.50 to 4.00) | 3.508 (1.00 to 11.98) | 3.000 (0.73 to 5.98) |
| C0D14 - BMS-813160 | 3.000 (0.55 to 3.03) | 1.825 (0.50 to 3.00) | 2.917 (0.92 to 15.70) | 2.983 (0.50 to 4.00) |
| C0D14 - BMS-939429 | 3.000 (0.98 to 4.00) | 1.825 (0.50 to 3.00) | 3.000 (1.08 to 15.70) | 2.983 (1.00 to 4.00) |
| C2D1 - BMS-813160 | 3.000 (0.98 to 4.23) | 1.000 (0.47 to 4.03) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| C2D1 - BMS-939429 | 3.000 (2.00 to 4.23) | 1.000 (0.97 to 4.03) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 6 |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| C0D1 - BMS-813160 | 2.492 (0.52 to 11.92) | 2.983 (0.58 to 8.92) | 3.00 (0.50 to 6.00) | 1.992 (0.50 to 3.00) |
| C0D1 - BMS-939429 | 3.000 (1.0 to 11.92) | 2.083 (1.08 to 8.92) | 3.000 (1.00 to 6.00) | 2.000 (0.98 to 4.00) |
| C0D14 - BMS-813160 | 2.875 (0.50 to 3.00) | 2.0 (1 to 3) | 2.000 (1.00 to 3.02) | 1.00 (0.5 to 4.0) |
| C0D14 - BMS-939429 | 2.875 (1.17 to 3.00) | 2.492 (1.98 to 3.00) | 3.000 (1.00 to 4.02) | 1.0 (1 to 6) |
| C2D1 - BMS-813160 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| C2D1 - BMS-939429 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150Q |
|---|---|---|---|---|

| | + NIVO | + NIVO | D + FOLFIRI | D + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 18 | 15 |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| C0D1 - BMS-813160 | 2.0 (2 to 2) | 3.950 (3.95 to 3.95) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| C0D1 - BMS-939429 | 2.0 (2 to 2) | 1.950 (1.95 to 1.95) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| C0D14 - BMS-813160 | 2.02 (2.02 to 2.02) | 2.542 (2.00 to 3.08) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| C0D14 - BMS-939429 | 2.02 (2.02 to 2.02) | 3.117 (2.00 to 4.23) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |
| C2D1 - BMS-813160 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 2.033 (0.50 to 14.10) | 2.067 (0.50 to 8.10) |
| C2D1 - BMS-939429 | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) | 99999 (99999 to 99999) |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[32] | 20 | 0[33] | 0[34] |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| C0D1 - BMS-813160 | ( to ) | 99999 (99999 to 99999) | ( to ) | ( to ) |
| C0D1 - BMS-939429 | ( to ) | 99999 (99999 to 99999) | ( to ) | ( to ) |
| C0D14 - BMS-813160 | ( to ) | 99999 (99999 to 99999) | ( to ) | ( to ) |
| C0D14 - BMS-939429 | ( to ) | 99999 (99999 to 99999) | ( to ) | ( to ) |
| C2D1 - BMS-813160 | ( to ) | 3.992 (0.50 to 16.17) | ( to ) | ( to ) |
| C2D1 - BMS-939429 | ( to ) | 99999 (99999 to 99999) | ( to ) | ( to ) |

Notes:

[32] - Tmax not calculated because there was an insufficient number of participants with evaluable data

[33] - Tmax not calculated because there was an insufficient number of participants with evaluable data

[34] - Tmax not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[35] | 0[36] | | |
| Units: Hours | | | | |
| median (full range (min-max)) | | | | |
| C0D1 - BMS-813160 | ( to ) | ( to ) | | |
| C0D1 - BMS-939429 | ( to ) | ( to ) | | |

| | | | | |
|---|---|---|---|---|
| C0D14 - BMS-813160 | ( to ) | ( to ) | | |
| C0D14 - BMS-939429 | ( to ) | ( to ) | | |
| C2D1 - BMS-813160 | ( to ) | ( to ) | | |
| C2D1 - BMS-939429 | ( to ) | ( to ) | | |

Notes:

[35] - Tmax not calculated because there was an insufficient number of participants with evaluable data

[36] - Tmax not calculated because there was an insufficient number of participants with evaluable data

### Statistical analyses

No statistical analyses for this end point

## Secondary: Trough Observed Plasma Concentration (Ctrough)

| End point title | Trough Observed Plasma Concentration (Ctrough) |
|---|---|

End point description:

Ctrough is defined as the concentration reached by a drug immediately before the next dose is administered

"99999"=N/A

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

End point timeframe:

From first dose up to prespecified timepoints, C0D1, C5D1, C0D1, C1D15, C5D1

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 3 | 4 | 4 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 283.70 (± 207.784) | 84.30 (± 46.169) | 292.0 (± 154.31) | 74.05 (± 72.127) |
| C5D1 - BMS-813160 | 268.80 (± 216.882) | 129.40 (± 89.944) | 176.0 (± 99999) | 15.30 (± 99999) |
| C0D1 - BMS-939429 | 172.63 (± 264.187) | 31.40 (± 10.689) | 180.88 (± 195.959) | 72.95 (± 55.542) |
| C1D15 - BMS 939429 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C5D1 - BMS-939429 | 55.78 (± 31.877) | 15.95 (± 4.172) | 155.0 (± 99999) | 10.50 (± 99999) |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 5 | 1 | 2 | 2 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|---|---|---|---|---|
| C0D1 - BMS-813160 | 157.28 (± 92.311) | 137.0 (± 99999) | 57.10 (± 54.871) | 5.485 (± 2.4395) |
| C5D1 - BMS-813160 | 323.0 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C0D1 - BMS-939429 | 47.60 (± 10.412) | 31.50 (± 99999) | 63.45 (± 60.175) | 4.950 (± 2.3052) |
| C1D15 - BMS 939429 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C5D1 - BMS-939429 | 65.20 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 11 | 16 |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 77.40 (± 99999) | 154.05 (± 139.936) | 99999 (± 99999) | 99999 (± 99999) |
| C5D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C0D1 - BMS-939429 | 90.30 (± 99999) | 71.65 (± 55.649) | 99999 (± 99999) | 99999 (± 99999) |
| C1D15 - BMS 939429 | 99999 (± 99999) | 99999 (± 99999) | 191.33 (± 84.266) | 24.106 (± 18.445) |
| C5D1 - BMS-939429 | 99999 (± 99999) | 99999 (± 99999) | 186.21 (± 131.457) | 12.439 (± 6.9685) |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 3 | 7 | 6 | 0[37] |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | () |
| C5D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | () |
| C0D1 - BMS-939429 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | () |
| C1D15 - BMS 939429 | 275.7 (± 164.34) | 116.04 (± 29.696) | 145.00 (± 99.293) | () |
| C5D1 - BMS-939429 | 195.0 (± 99999) | 191.44 (± 113.725) | 222.65 (± 154.316) | () |

Notes:

[37] - Ctrough not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 2-Arm C- | Part 2-Arm C- | | |
|---|---|---|---|---|

| | Cohort 4: 2L PC/BMS300BID + NIVO | Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1 | 1 | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | | |
| C5D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | | |
| C0D1 - BMS-939429 | 99999 (± 99999) | 99999 (± 99999) | | |
| C1D15 - BMS 939429 | 283.0 (± 99999) | 99999 (± 99999) | | |
| C5D1 - BMS-939429 | 99999 (± 99999) | 390.0 (± 99999) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under Curve (AUC) 0-8

| End point title | Area Under Curve (AUC) 0-8 |
|---|---|

End point description:

Area Under Curve (AUC) is defined as the area under the plot of plasma concentration of a drug versus time after dosage measured at 8 hours post-dose

"99999"=N/A

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

End point timeframe:

From first dose up to prespecified timepoints- C0D1, C2D1

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 7 | 10 | 10 |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 2300.018 (± 976.4608) | 7069.265 (± 2452.4213) | 2725.390 (± 1365.3562) | 7884.381 (± 3968.4940) |
| C0D1 - BMS-939429 | 652.848 (± 363.5925) | 1783.336 (± 856.0103) | 936.394 (± 826.5807) | 2302.092 (± 1023.3978) |
| C2D1 - BMS-813160 | 5348.973 (± 2506.2558) | 11967.560 (± 4586.3823) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-939429 | 1410.415 (± 837.4895) | 2403.182 (± 1144.3271) | 99999 (± 99999) | 99999 (± 99999) |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 6 |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 1534.932 (± 518.2172) | 6593.904 (± 3603.5286) | 3533.737 (± 1931.7752) | 878.051 (± 535.3197) |
| C0D1 - BMS-939429 | 342.534 (± 157.1350) | 2147.888 (± 1415.6386) | 942.398 (± 620.1018) | 210.938 (± 106.5352) |
| C2D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-939429 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 1 | 9 | 13 |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 4440.313 (± 99999) | 3656.713 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C0D1 - BMS-939429 | 1919.228 (± 99999) | 411.410 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 4838.264 (± 2750.7756) | 1483.423 (± 1236.0374) |
| C2D1 - BMS-939429 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[38] | 14 | 0[39] | 0[40] |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | 99999 (± 99999) | () | () |
| C0D1 - BMS-939429 | () | 99999 (± 99999) | () | () |
| C2D1 - BMS-813160 | () | 3821.887 (± 2221.2474) | () | () |

| | | | | |
|---|---|---|---|---|
| C2D1 - BMS-939429 | () | 99999 (± 99999) | () | () |

Notes:

[38] - AUC not calculated because there was an insufficient number of participants with evaluable data

[39] - AUC not calculated because there was an insufficient number of participants with evaluable data

[40] - AUC not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1 | 0[41] | | |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 99999 (± 99999) | () | | |
| C0D1 - BMS-939429 | 99999 (± 99999) | () | | |
| C2D1 - BMS-813160 | 99999 (± 99999) | () | | |
| C2D1 - BMS-939429 | 99999 (± 99999) | () | | |

Notes:

[41] - AUC not calculated because there was an insufficient number of participants with evaluable data

## Statistical analyses

No statistical analyses for this end point

## Secondary: Area Under Curve (AUC) 0-24

| End point title | Area Under Curve (AUC) 0-24 |
|---|---|

End point description:

Area Under Curve (AUC) is defined as the area under the plot of plasma concentration of a drug versus time after dosage measured at 8 hours post-dose

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

End point timeframe:

From first dose up to prespecified timepoints-C0D1, C2D1

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[42] | 7 | 0[43] | 9 |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | 9383.385 (± 2842.8397) | () | 11726.669 (± 6439.1376) |
| C0D1 - BMS-939429 | () | 2638.062 (± 977.2502) | () | 3991.522 (± 1636.3573) |

| | | | | |
|---|---|---|---|---|
| C2D1 - BMS-813160 | () | 17890.458 (± 9212.5646) | () | 99999 (± 99999) |
| C2D1 - BMS-939429 | () | 3958.779 (± 1632.3781) | () | 99999 (± 99999) |

Notes:

[42] - AUC not calculated because there was an insufficient number of participants with evaluable data

[43] - AUC not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[44] | 5 | 7 | 6 |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | 10447.179 (± 2995.9347) | 4829.881 (± 2696.4668) | 1275.314 (± 799.8262) |
| C0D1 - BMS-939429 | () | 3905.941 (± 1852.8415) | 1660.159 (± 991.0121) | 341.0396 (± 160.4425) |
| C2D1 - BMS-813160 | () | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-939429 | () | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

Notes:

[44] - AUC not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[45] | 1 | 0[46] | 11 |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | 7687.658 (± 99999) | () | 99999 (± 99999) |
| C0D1 - BMS-939429 | () | 940.294 (± 99999) | () | 99999 (± 99999) |
| C2D1 - BMS-813160 | () | 99999 (± 99999) | () | 2050.804 (± 997.6990) |
| C2D1 - BMS-939429 | () | 99999 (± 99999) | () | 99999 (± 99999) |

Notes:

[45] - AUC not calculated because there was an insufficient number of participants with evaluable data

[46] - AUC not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[47] | 0[48] | 0[49] | 0[50] |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | () | () | () |

| | | | | |
|---|---|---|---|---|
| C0D1 - BMS-939429 | () | () | () | () |
| C2D1 - BMS-813160 | () | () | () | () |
| C2D1 - BMS-939429 | () | () | () | () |

Notes:

[47] - AUC not calculated because there was an insufficient number of participants with evaluable data

[48] - AUC not calculated because there was an insufficient number of participants with evaluable data

[49] - AUC not calculated because there was an insufficient number of participants with evaluable data

[50] - AUC not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[51] | 0[52] | | |
| Units: ug*h/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | () | | |
| C0D1 - BMS-939429 | () | () | | |
| C2D1 - BMS-813160 | () | () | | |
| C2D1 - BMS-939429 | () | () | | |

Notes:

[51] - AUC not calculated because there was an insufficient number of participants with evaluable data

[52] - AUC not calculated because there was an insufficient number of participants with evaluable data

### Statistical analyses

No statistical analyses for this end point

## Secondary: Apparent Total Body Clearance (CLT/F)

| End point title | Apparent Total Body Clearance (CLT/F) |
|---|---|

End point description:

The total body clearance (CLT/F) is defined as the volume of plasma completely cleared of drug per unit time.

"99999"=N/A

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

End point timeframe:

From first dose up to prespecified timepoints-C0D1, C2D14

| **End point values** | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 5 | 7 | 4 |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D14 - BMS-813160 | 1163.173 (± 588.1385) | 744.746 (± 361.5390) | 1521.863 (± 1277.8075) | 826.468 (± 300.1738) |
| C2D1 - BMS-813160 | 956.446 (± 596.7553) | 683.958 (± 322.7045) | 99999 (± 99999) | 99999 (± 99999) |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 6 | 2 | 3 | 2 |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D14 - BMS-813160 | 1602.009 (± 1123.8919) | 961.379 (± 235.4622) | 1688.813 (± 1022.7160) | 4950.110 (± 781.0155) |
| C2D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) | 99999 (± 99999) |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 9 | 13 |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D14 - BMS-813160 | 1135.947 (± 99999) | 1032.434 (± 850.2203) | 99999 (± 99999) | 99999 (± 99999) |
| C2D1 - BMS-813160 | 99999 (± 99999) | 99999 (± 99999) | 1115.087 (± 851.2513) | 1813.987 (± 1920.2627) |

| End point values | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[53] | 10 | 0[54] | 0[55] |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D14 - BMS-813160 | () | 99999 (± 99999) | () | () |
| C2D1 - BMS-813160 | () | 1440.516 (± 733.5156) | () | () |

Notes:

[53] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

[54] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

[55] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

| End point values | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + | | |
|---|---|---|---|---|

| | | NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 0[56] | 0[57] | | |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D14 - BMS-813160 | () | () | | |
| C2D1 - BMS-813160 | () | () | | |

Notes:

[56] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

[57] - CLT/F not calculated because there was an insufficient number of participants with evaluable data

## Statistical analyses

No statistical analyses for this end point

## Secondary: Renal Clearance (CLR)

| End point title | Renal Clearance (CLR) |
|---|---|

End point description:

Renal clearance is defined as the rate at which the analytes were removed from the plasma by the kidneys.

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

End point timeframe:

From first dose up to prespecified timepoints-C0D1, C0D14

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 4 | 6 | 3 |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | 212.411 (± 191.8961) | 275.309 (± 277.2659) | 139.012 (± 107.2006) | 165.327 (± 77.8766) |
| C0D1 - BMS-939429 | 74.298 (± 44.8889) | 175.109 (± 187.5683) | 68.184 (± 52.1580) | 77.744 (± 34.8177) |
| C0D14 - BMS-813160 | 185.926 (± 56.5866) | 124.400 (± 52.1454) | 260.786 (± 120.8954) | 168.274 (± 72.7581) |
| C0D14 - BMS-939429 | 101.042 (± 27.5043) | 76.285 (± 30.5071) | 145.662 (± 73.3215) | 91.490 (± 43.8006) |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 7 | 3 | 5 | 4 |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|---|---|---|---|---|
| C0D1 - BMS-813160 | 155.820 (± 119.3858) | 181.930 (± 9.1130) | 248.003 (± 82.6974) | 236.781 (± 62.8689) |
| C0D1 - BMS-939429 | 81.027 (± 65.1050) | 98.733 (± 6.2562) | 140.597 (± 41.7347) | 128.943 (± 26.7782) |
| C0D14 - BMS-813160 | 158.238 (± 82.5905) | 194.009 (± 50.1111) | 283.842 (± 109.4518) | 149.271 (± 72.0204) |
| C0D14 - BMS-939429 | 87.068 (± 43.9667) | 111.649 (± 32.4552) | 99999 (± 99999) | 99999 (± 99999) |

| **End point values** | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID + NIVO | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD + NIVO | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BID + FOLFIRI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[58] | 1 | 0[59] | 0[60] |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | 99999 (± 99999) | () | () |
| C0D1 - BMS-939429 | () | 62.007 (± 99999) | () | () |
| C0D14 - BMS-813160 | () | 115.147 (± 99999) | () | () |
| C0D14 - BMS-939429 | () | 99999 (± 99999) | () | () |

Notes:

[58] - CLR not calculated because there was an insufficient number of participants with evaluable data

[59] - CLR not calculated because there was an insufficient number of participants with evaluable data

[60] - CLR not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 0[61] | 0[62] | 0[63] | 0[64] |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | () | () | () |
| C0D1 - BMS-939429 | () | () | () | () |
| C0D14 - BMS-813160 | () | () | () | () |
| C0D14 - BMS-939429 | () | () | () | () |

Notes:

[61] - CLR not calculated because there was an insufficient number of participants with evaluable data

[62] - CLR not calculated because there was an insufficient number of participants with evaluable data

[63] - CLR not calculated because there was an insufficient number of participants with evaluable data

[64] - CLR not calculated because there was an insufficient number of participants with evaluable data

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|

| Subject group type | Reporting group | Reporting group | | |
|---|---|---|---|---|
| Number of subjects analysed | 0[65] | 0[66] | | |
| Units: mL/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| C0D1 - BMS-813160 | () | () | | |
| C0D1 - BMS-939429 | () | () | | |
| C0D14 - BMS-813160 | () | () | | |
| C0D14 - BMS-939429 | () | () | | |

Notes:

[65] - CLR not calculated because there was an insufficient number of participants with evaluable data

[66] - CLR not calculated because there was an insufficient number of participants with evaluable data

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants who were Anti-Drug Antibody (ADA) Positive

| End point title | Number of Participants who were Anti-Drug Antibody (ADA) Positive |
|---|---|

End point description:

The number of participants who are anti-drug antibody positive. ADA-positive participant is a participant with at least 1 ADA-positive sample relative to baseline after initiation of the treatment. ADA-positive sample is in a participant who is baseline ADA negative or with an ADA titer to be at least 4-fold or greater than baseline positive titer.

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

End point timeframe:

From first dose up to prespecified timepoints-C1D1, C1D15, C2D1, C3D1, C5D1, C9D1

| End point values | Part 1-Arm A-Cohort 1: 1L CRC/BMS300BID + FOLFIRI | Part 1-Arm A-Cohort 2: 1L CRC/BMS600QD + FOLFIRI | Part 1-Arm B-Cohort 1: 1L PC/BMS300BID + GEM/NAB | Part 1-Arm B-Cohort 2: 1L PC/BMS600QD + GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 10 | 8 | 10 | 11 |
| Units: Participants | 0 | 0 | 0 | 0 |

| End point values | Part 1-Arm C-Cohort 1: 2/3L CRC MSS/BMS300BID + NIVO | Part 1-Arm C-Chort 2: 2/3L CRC MSS/BMS600QD + NIVO | Part 1-Arm C-Chort 3: 2/3L CRC MSS/BMS300QD + NIVO | Part 1-Arm C-Cohort 4: 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 8 | 7 | 7 | 11 |
| Units: Participants | 0 | 0 | 1 | 0 |

| End point values | Part 1-Arm C-Cohort 5: 2L PC/BMS300BID | Part 1-Arm C-Cohort 6: 2L PC/BMS600QD | Part 2-Arm A-Cohort 1a: 2L CRC/BMS300BI | Part 2-Arm A-Cohort 1b: 2L CRC/BMS150Q |
|---|---|---|---|---|

| | + NIVO | + NIVO | D + FOLFIRI | D + FOLFIRI |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 1 | 2 | 32 | 32 |
| Units: Participants | 0 | 0 | 0 | 0 |

| **End point values** | Part 2-Arm A-Cohort 1C: 2L CRC/FOLFIRI | Part 2-Arm B-Cohort 3a: 1L PC/BMS300BID + GEM/NAB | Part 2-Arm B-Cohort 3b: 1L PC/BMS300BID + GEM/NAB + NIVO | Part 2-Arm B-Cohort 3C: 1L PC/GEM/NAB |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 26 | 35 | 35 | 32 |
| Units: Participants | 0 | 0 | 0 | 0 |

| **End point values** | Part 2-Arm C-Cohort 4: 2L PC/BMS300BID + NIVO | Part 2-Arm C-Cohort 5: 2/3L CRC MSS /BMS300BID + NIVO | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 24 | 33 | | |
| Units: Participants | 0 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for all-cause mortality from their randomization to study completion, (up to approximately 5.5 years). SAEs and NSAEs were assessed from first dose to 100 days following last dose (up to approximately 3 years).

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

## Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 26.0 |

## Reporting groups

| | |
|---|---|
| Reporting group title | P1 1L CRC/BMS300BID + FOLFIRI |

Reporting group description:

First-line treatment BMS-813160 300 mg twice a day in combination with FOLFIRI in participants with metastatic colorectal cancer

| | |
|---|---|
| Reporting group title | P1 1L PC/BMS600QD + GEM/NAB |

Reporting group description:

First-line treatment BMS-813160 600 mg once a day in combination with Gem/ nab-paclitaxel (ABRAXANE)

| | |
|---|---|
| Reporting group title | P1 1L PC/BMS300BID + GEM/NAB |

Reporting group description:

First-line treatment BMS-813160 300 mg twice a day in combination with Gem/nab-paclitaxel (ABRAXANE) in participants with pancreatic cancer

| | |
|---|---|
| Reporting group title | P1 1L CRC/BMS600QD + FOLFIRI |

Reporting group description:

First-line treatment BMS-813160 600 mg once a day in combination with FOLFIRI in participants with metastatic colorectal cancer

| | |
|---|---|
| Reporting group title | P1 2L PC/BMS300BID + NIVO |

Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

| | |
|---|---|
| Reporting group title | P1 2/3L CRC MSS/BMS150QD + NIVO |

Reporting group description:

Second- and third-line treatment BMS-813160 150mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| | |
|---|---|
| Reporting group title | P1 2/3L CRC MSS/BMS300QD + NIVO |

Reporting group description:

Second- and third-line treatment BMS-813160 300mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| | |
|---|---|
| Reporting group title | P1 2/3L CRC MSS/BMS600QD + NIVO |

Reporting group description:

Second- and third-line treatment BMS-813160 600mg once a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| | |
|---|---|
| Reporting group title | P1 2/3L CRC MSS/BMS300BID + NIVO |

Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice a day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| | |
|---|---|
| Reporting group title | P1 2L PC/BMS600QD + NIVO |

Reporting group description:

Second-line treatment BMS-813160 600mg once per day in combination with nivolumab in participants with pancreatic cancer

| | |
|---|---|
| Reporting group title | P2 1L PC/BMS300BID + GEM/NAB + NIVO |

Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel and nivolumab in participants with pancreatic cancer

| Reporting group title | P2 1L PC/BMS300BID + GEM/NAB |
|---|---|

Reporting group description:

First-line treatment BMS-813160 300mg twice per day in combination with gemcitabine/nab-paclitaxel in participants with pancreatic cancer

| Reporting group title | P2 2L CRC/FOLFIRI |
|---|---|

Reporting group description:

Second-line treatment FOLFIRI in participants with colorectal cancer

| Reporting group title | P2 2L CRC/BMS300BID + FOLFIRI |
|---|---|

Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with FOLFIRI in participants with colorectal cancer

| Reporting group title | P2 2L CRC/BMS150QD + FOLFIRI |
|---|---|

Reporting group description:

Second-line treatment BMS-813160 150mg once per day in combination with FOLFIRI in participants with colorectal cancer

| Reporting group title | P2 1L PC/GEM/NAB |
|---|---|

Reporting group description:

First-line treatment gemcitabine/ nab-paclitaxel in participants with pancreatic cancer

| Reporting group title | P2 2/3L CRC MSS /BMS300BID + NIVO |
|---|---|

Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| Reporting group title | P2 2L PC/BMS300BID + NIVO |
|---|---|

Reporting group description:

Second-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with pancreatic cancer

| Reporting group title | P2 2L CRC /FOLFIRI P2 2/3L CRC MSS/BMS300BID + NIVO |
|---|---|

Reporting group description:

Second- and third-line treatment BMS-813160 300mg twice per day in combination with nivolumab in participants with microsatellite stable colorectal cancer

| **Serious adverse events** | P1 1L CRC/BMS300BID + FOLFIRI | P1 1L PC/BMS600QD + GEM/NAB | P1 1L PC/BMS300BID + GEM/NAB |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 10 (50.00%) | 7 / 11 (63.64%) | 5 / 10 (50.00%) |
| number of deaths (all causes) | 6 | 8 | 8 |
| number of deaths resulting from adverse events | 0 | 1 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Histiocytic necrotising lymphadenitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Death | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 3 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostatic haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cough | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 2 / 10 (20.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary oedema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| White blood cell count increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural bile leak | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrong product administered | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial flutter | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac arrest | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Left ventricular failure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stress cardiomyopathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intracranial mass | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Anaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Duodenal stenosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant gastrointestinal obstruction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (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 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Portal hypertension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Panniculitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis infective | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fournier's gangrene | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis sapovirus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphangitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rectal abscess | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scrotal abscess | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Splenic infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spontaneous bacterial peritonitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | P1 1L CRC/BMS600QD + FOLFIRI | P1 2L PC/BMS300BID + NIVO | P1 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 8 (62.50%) | 1 / 1 (100.00%) | 6 / 11 (54.55%) |
| number of deaths (all causes) | 6 | 1 | 7 |
| number of deaths resulting from adverse events | 0 | 1 | 4 |

| | | | |
|---|---|---|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Histiocytic necrotising lymphadenitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 1 (100.00%) | 4 / 11 (36.36%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 4 / 4 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | | | |
| Death | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 like illness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostatic haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 bilirubin increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 1 (100.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| White blood cell count increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 procedural bile leak | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 procedural complication | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrong product administered | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 flutter | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intracranial mass | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ascites | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematochezia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant gastrointestinal obstruction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oesophagitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary obstruction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 | | | |
| Panniculitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hydronephrosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 obstruction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| **Musculoskeletal and connective tissue disorders** | | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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** | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary tract infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| COVID-19 | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis infective | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 bacteraemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium difficile infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fournier's gangrene | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 sapovirus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphangitis | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary sepsis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scrotal abscess | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Splenic infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spontaneous bacterial peritonitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suspected COVID-19 | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| 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** | P1 2/3L CRC MSS/BMS300QD + NIVO | P1 2/3L CRC MSS/BMS600QD + NIVO | P1 2/3L CRC MSS/BMS300BID + NIVO |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 7 (85.71%) | 6 / 7 (85.71%) | 5 / 8 (62.50%) |
| number of deaths (all causes) | 6 | 6 | 6 |
| number of deaths resulting from adverse events | 5 | 4 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Histiocytic necrotising lymphadenitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 5 / 7 (71.43%) | 3 / 7 (42.86%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 5 / 5 | 3 / 3 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 disorders | | | |
| Deep vein thrombosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Embolism | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | 0 / 7 (0.00%) | 0 / 7 (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 |
| General disorders and administration site conditions | | | |
| Death | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | 1 / 1 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 like illness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Prostatic haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |

| | | | |
|---|---|---|---|
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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** | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 / 7 (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 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |

| | | | |
|---|---|---|---|
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 | 1 / 7 (14.29%) | 0 / 7 (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 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 bilirubin increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (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 |

| | | | |
|---|---|---|---|
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| White blood cell count increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |

| | | | |
|---|---|---|---|
| Post procedural bile leak | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 compression fracture | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Wrong product administered | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 flutter | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Left ventricular failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hepatic encephalopathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Intracranial mass | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Seizure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Abdominal pain upper | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Ascites | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Colitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Constipation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 / 7 (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 haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Malignant gastrointestinal obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Melaena | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 / 7 (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 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Small intestinal obstruction | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Cholangitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | | | |
| Panniculitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Rash | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Haematuria | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Flank pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (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 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |

| | | | |
|---|---|---|---|
| Biliary tract infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 viral | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Cholangitis infective | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Fournier's gangrene | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| 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 sapovirus | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hepatic infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Lymphangitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Peritonitis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (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 |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 / 7 (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 |
| Scrotal abscess | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |
| Splenic infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Spontaneous bacterial peritonitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 / 7 (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 / 7 (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 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hypernatraemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (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 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 |
| Hypoglycaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (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 / 7 (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 |

| **Serious adverse events** | P1 2L PC/BMS600QD + NIVO | P2 1L PC/BMS300BID + GEM/NAB + NIVO | P2 1L PC/BMS300BID + GEM/NAB |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 2 (100.00%) | 22 / 35 (62.86%) | 24 / 35 (68.57%) |
| number of deaths (all causes) | 2 | 34 | 33 |
| number of deaths resulting from adverse events | 2 | 4 | 3 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Histiocytic necrotising lymphadenitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 2 / 2 (100.00%) | 2 / 35 (5.71%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 2 / 2 | 1 / 1 | 0 / 0 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (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 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Death | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 5 / 35 (14.29%) | 4 / 35 (11.43%) |
| occurrences causally related to treatment / all | 0 / 0 | 5 / 10 | 3 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Prostatic haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| **Respiratory, thoracic and mediastinal disorders** | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 2 / 35 (5.71%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 bilirubin increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (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 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| White blood cell count increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 procedural bile leak | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 procedural complication | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrong product administered | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| 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 | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial flutter | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Left ventricular failure | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| Dizziness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intracranial mass | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 2 / 2 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 3 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| 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 haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant gastrointestinal obstruction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Melaena | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (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 |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary obstruction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (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 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 | | | |
| Panniculitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 1 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 obstruction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| 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 | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary tract infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis infective | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 2 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Clostridium difficile infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fournier's gangrene | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 sapovirus | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphangitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Rectal abscess | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scrotal abscess | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 2 / 35 (5.71%) | 5 / 35 (14.29%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 2 / 5 |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Splenic infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spontaneous bacterial peritonitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| 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 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | P2 2L CRC/FOLFIRI | P2 2L CRC/BMS300BID + FOLFIRI | P2 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 17 (23.53%) | 12 / 32 (37.50%) | 12 / 32 (37.50%) |
| number of deaths (all causes) | 10 | 26 | 28 |
| number of deaths resulting from adverse events | 0 | 0 | 1 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Histiocytic necrotising lymphadenitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant neoplasm progression | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metastases to central nervous system | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Death | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 like illness | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostatic haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Confusional state | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Investigations | | | |

| | | | |
|---|---|---|---|
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 bilirubin increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| White blood cell count increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Hip fracture | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (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 |
| Post procedural bile leak | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 procedural complication | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrong product administered | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 | | | |

| | | | |
|---|---|---|---|
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 flutter | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| 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 arrest | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| 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 | | | |
| Altered state of consciousness | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 2 / 32 (6.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intracranial mass | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 3 / 32 (9.38%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant gastrointestinal obstruction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Melaena | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (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 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 3 / 32 (9.38%) | 2 / 32 (6.25%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 6 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary obstruction | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 | | | |
| Panniculitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary tract infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis infective | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 bacteraemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fournier's gangrene | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 sapovirus | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphangitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scrotal abscess | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Splenic infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spontaneous bacterial peritonitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypernatraemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| 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** | P2 1L PC/GEM/NAB | P2 2/3L CRC MSS /BMS300BID + NIVO | P2 2L PC/BMS300BID + NIVO |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 15 / 32 (46.88%) | 14 / 24 (58.33%) | 17 / 24 (70.83%) |
| number of deaths (all causes) | 26 | 18 | 20 |
| number of deaths resulting from adverse events | 3 | 5 | 8 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Histiocytic necrotising lymphadenitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (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 |
| Malignant neoplasm progression | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 32 (3.13%) | 5 / 24 (20.83%) | 7 / 24 (29.17%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 5 | 0 / 7 |
| deaths causally related to treatment / all | 1 / 1 | 5 / 5 | 7 / 7 |
| Metastases to central nervous system | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Squamous cell carcinoma of skin | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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** | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 2 / 24 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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** | | | |
| Death | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Fatigue | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 3 / 24 (12.50%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General physical health deterioration | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 like illness | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Prostatic haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory distress syndrome | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoxia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 2 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| Pneumothorax | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (3.13%) | 0 / 24 (0.00%) | 3 / 24 (12.50%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary oedema | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| 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 | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| 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 bilirubin increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic enzyme increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Streptococcus test positive | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| White blood cell count increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 procedural bile leak | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spinal compression fracture | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Transfusion reaction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Wrong product administered | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Atrial flutter | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pericardial effusion | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Stress cardiomyopathy | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |

| | | | |
|---|---|---|---|
| Altered state of consciousness | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 2 / 24 (8.33%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic encephalopathy | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intracranial mass | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile neutropenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (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 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 2 / 24 (8.33%) | 3 / 24 (12.50%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | 0 / 4 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Diarrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 2 / 24 (8.33%) | 0 / 24 (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 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower gastrointestinal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestinal obstruction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Malignant gastrointestinal obstruction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 3 / 24 (12.50%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Proctalgia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | 1 / 32 (3.13%) | 2 / 24 (8.33%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 2 / 24 (8.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Autoimmune hepatitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary obstruction | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |

| | | | |
|---|---|---|---|
| Panniculitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (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 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Flank pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | | | |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Biliary tract infection | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| COVID-19 pneumonia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cholangitis infective | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fournier's gangrene | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 sapovirus | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatic infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Klebsiella bacteraemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Liver abscess | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lymphangitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | 3 / 32 (9.38%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Peritonitis bacterial | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pulmonary sepsis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Scrotal abscess | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (3.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Splenic infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Spontaneous bacterial peritonitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suspected COVID-19 | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dehydration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| 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** | P2 2L CRC /FOLFIRI P2 2/3L CRC MSS/BMS300BID + NIVO | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 5 / 9 (55.56%) | | |
| number of deaths (all causes) | 7 | | |
| number of deaths resulting from adverse events | 1 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Cancer pain | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Histiocytic necrotising lymphadenitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Malignant neoplasm progression | | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 1 / 1 | | | |
| Metastases to central nervous system | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Squamous cell carcinoma of skin | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vascular disorders | | | | |
| Deep vein thrombosis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Embolism | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypotension | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| General disorders and administration site conditions | | | | |

| | | | | |
|---|---|---|---|---|
| Death | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gait disturbance | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fatigue | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| General physical health deterioration | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza like illness | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Non-cardiac chest pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oedema peripheral | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peripheral swelling | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyrexia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Immune system disorders | | | | |
| Anaphylactic reaction | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Reproductive system and breast disorders | | | | |
| Balanoposthitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Prostatic haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vaginal haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory, thoracic and mediastinal disorders | | | | |
| Acute respiratory distress syndrome | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Acute respiratory failure | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cough | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dyspnoea | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hypoxia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleural effusion | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pleuritic pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumothorax | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary embolism | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary oedema | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory failure | | | | |
| subjects affected / exposed | 0 / 9 (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 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Investigations | | | | |
| Alanine aminotransferase increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Blood bilirubin increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Aspartate aminotransferase increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatic enzyme increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|---|---|---|---|---|
| Neutrophil count decreased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Streptococcus test positive | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| White blood cell count increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Injury, poisoning and procedural complications | | | | |
| Fall | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hip fracture | | | | |
| subjects affected / exposed | 0 / 9 (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 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post procedural bile leak | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post procedural complication | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|---|---|---|---|---|
| Spinal compression fracture | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tibia fracture | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Transfusion reaction | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Wrong product administered | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac disorders | | | | |
| Atrial fibrillation | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Atrial flutter | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac arrest | | | | |
| subjects affected / exposed | 0 / 9 (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 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pericardial effusion | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Stress cardiomyopathy | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders | | | | |
| Altered state of consciousness | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cerebral haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cerebrovascular accident | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dizziness | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatic encephalopathy | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intracranial mass | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Seizure | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ascites | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Anal haemorrhage | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Colitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Diarrhoea | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Constipation | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Duodenal stenosis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Enterocolitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haematochezia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ileus | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Intestinal obstruction | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lower gastrointestinal haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Large intestinal obstruction | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Malignant gastrointestinal obstruction | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Melaena | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nausea | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Oesophagitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pancreatitis | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rectal haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Proctalgia | | | | |
| subjects affected / exposed | 0 / 9 (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 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Vomiting | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatobiliary disorders | | | | |
| Autoimmune hepatitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholangitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Biliary obstruction | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatitis | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Portal hypertension | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin and subcutaneous tissue disorders | | | | |
| Panniculitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rash | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rash maculo-papular | | | | |
| subjects affected / exposed | 0 / 9 (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 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haematuria | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hydronephrosis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary tract obstruction | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (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 | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Flank pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Muscular weakness | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| Appendicitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bacteraemia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Biliary tract infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| COVID-19 | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |

| | | | | |
|---|---|---|---|---|
| Bronchitis viral | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| COVID-19 pneumonia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cholangitis infective | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Escherichia bacteraemia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Clostridium difficile infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fournier's gangrene | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis sapovirus | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatic infection | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Klebsiella bacteraemia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Liver abscess | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Lymphangitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peritonitis bacterial | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pulmonary sepsis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rectal abscess | | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Scrotal abscess | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skin infection | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Splenic infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Spontaneous bacterial peritonitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Suspected COVID-19 | | | | |
| subjects affected / exposed | 0 / 9 (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 / 9 (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 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 9 (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** | P1 1L CRC/BMS300BID + FOLFIRI | P1 1L PC/BMS600QD + GEM/NAB | P1 1L PC/BMS300BID + GEM/NAB |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 10 (100.00%) | 11 / 11 (100.00%) | 9 / 10 (90.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Embolism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Hypotension | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 3 / 11 (27.27%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Lymphorrhoea | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Superficial vein thrombosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Venous thrombosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 6 / 10 (60.00%) | 5 / 11 (45.45%) | 7 / 10 (70.00%) |
| occurrences (all) | 22 | 7 | 9 |
| Cyst | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 5 / 11 (45.45%) | 1 / 10 (10.00%) |
| occurrences (all) | 2 | 7 | 1 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 5 | 1 |
| Swelling | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Perineal pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scrotal pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 2 | 2 | 2 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 2 / 10 (20.00%) |
| occurrences (all) | 2 | 1 | 2 |
| Cough | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 2 | 3 |
| Dysphonia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hiccups | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Nasal inflammation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinorrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Delusion | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 3 / 10 (30.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Sleep disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 4 / 11 (36.36%) | 3 / 10 (30.00%) |
| occurrences (all) | 0 | 5 | 6 |
| Amylase increased | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 3 / 10 (30.00%) |
| occurrences (all) | 1 | 2 | 5 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 3 / 11 (27.27%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 3 | 4 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| International normalised ratio increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 4 / 10 (40.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 7 | 2 | 2 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 4 | 1 | 4 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 3 / 10 (30.00%) |
| occurrences (all) | 1 | 0 | 3 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 11 (18.18%) | 2 / 10 (20.00%) |
| occurrences (all) | 3 | 4 | 2 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 4 / 11 (36.36%) | 2 / 10 (20.00%) |
| occurrences (all) | 1 | 15 | 3 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 11 (18.18%) | 2 / 10 (20.00%) |
| occurrences (all) | 2 | 4 | 7 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Infusion related reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Stoma site pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site oedema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site ulcer | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site rash | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cardiac dysfunction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholinergic syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 2 / 10 (20.00%) |
| occurrences (all) | 15 | 1 | 2 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 14 | 1 | 1 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 2 / 10 (20.00%) |
| occurrences (all) | 1 | 1 | 4 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 2 / 10 (20.00%) |
| occurrences (all) | 2 | 1 | 2 |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Peripheral motor neuropathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 1 / 10 (10.00%) |
| occurrences (all) | 4 | 3 | 1 |
| Tremor | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 4 / 10 (40.00%) | 5 / 11 (45.45%) | 5 / 10 (50.00%) |
| occurrences (all) | 9 | 9 | 6 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 11 (18.18%) | 1 / 10 (10.00%) |
| occurrences (all) | 3 | 6 | 7 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blepharospasm | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Lacrimation increased | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Photophobia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Photopsia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitreous floaters | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 3 / 11 (27.27%) | 4 / 10 (40.00%) |
| occurrences (all) | 1 | 3 | 8 |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal inflammation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anorectal discomfort | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal rash | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |

| | | | |
|---|---|---|---|
| Constipation | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 3 / 11 (27.27%) | 5 / 10 (50.00%) |
| occurrences (all) | 3 | 5 | 7 |
| Colitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Defaecation urgency | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 7 / 10 (70.00%) | 2 / 11 (18.18%) | 3 / 10 (30.00%) |
| occurrences (all) | 18 | 3 | 3 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyschezia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 3 / 11 (27.27%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Faeces discoloured | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 2 / 11 (18.18%) | 1 / 10 (10.00%) |
| occurrences (all) | 2 | 2 | 1 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Nausea | | | |
| subjects affected / exposed | 5 / 10 (50.00%) | 7 / 11 (63.64%) | 4 / 10 (40.00%) |
| occurrences (all) | 21 | 8 | 5 |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral dysaesthesia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Vomiting | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 3 / 11 (27.27%) | 4 / 10 (40.00%) |
| occurrences (all) | 3 | 4 | 6 |
| Stomatitis | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Hepatobiliary disorders | | | |
| Hepatic pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypertransaminasaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 3 / 11 (27.27%) | 2 / 10 (20.00%) |
| occurrences (all) | 3 | 3 | 2 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nail ridging | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nail discolouration | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |

| | | | |
|---|---|---|---|
| Night sweats | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 3 / 11 (27.27%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 3 | 6 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 2 | 1 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 3 / 11 (27.27%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin hyperpigmentation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Xeroderma | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Renal and urinary disorders | | | |
| Bladder pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chromaturia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proteinuria | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|---|---|---|---|
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 2 | 2 | 1 |
| Back pain | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 2 / 10 (20.00%) |
| occurrences (all) | 1 | 2 | 4 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 1 | 3 |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Anorectal infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 2 / 10 (20.00%) |
| occurrences (all) | 0 | 0 | 3 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Cystitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobacter infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 2 | 0 | 1 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 1 | 1 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Rash pustular | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pyuria | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Gout | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 2 | 1 | 1 |
| Decreased appetite | | | |
| subjects affected / exposed | 3 / 10 (30.00%) | 5 / 11 (45.45%) | 2 / 10 (20.00%) |
| occurrences (all) | 20 | 5 | 2 |
| Hypercalcaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 0 | 1 |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 2 / 10 (20.00%) |
| occurrences (all) | 1 | 1 | 5 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 3 / 11 (27.27%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 4 | 2 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 1 / 11 (9.09%) | 3 / 10 (30.00%) |
| occurrences (all) | 1 | 1 | 5 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperphosphataemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 1 | 1 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 4 / 11 (36.36%) | 1 / 10 (10.00%) |
| occurrences (all) | 0 | 5 | 1 |
| Hypomagnesaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 10 (30.00%) | 2 / 11 (18.18%) | 0 / 10 (0.00%) |
| occurrences (all) | 8 | 3 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | 2 / 11 (18.18%) | 1 / 10 (10.00%) |
| occurrences (all) | 1 | 2 | 1 |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 1 / 11 (9.09%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | 0 / 11 (0.00%) | 0 / 10 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | P1 1L CRC/BMS600QD + FOLFIRI | P1 2L PC/BMS300BID + NIVO | P1 2/3L CRC MSS/BMS150QD + NIVO |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 8 / 8 (100.00%) | 1 / 1 (100.00%) | 10 / 11 (90.91%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Embolism | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphorrhoea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Superficial vein thrombosis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 4 / 8 (50.00%) | 0 / 1 (0.00%) | 4 / 11 (36.36%) |
| occurrences (all) | 4 | 0 | 4 |
| Cyst | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 1 (100.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 1 (100.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 3 / 11 (27.27%) |
| occurrences (all) | 1 | 0 | 3 |
| Swelling | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Perineal pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Scrotal pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 1 (100.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cough | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 3 | 0 | 1 |
| Dysphonia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hiccups | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasal inflammation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 2 / 11 (18.18%) |
| occurrences (all) | 0 | 0 | 2 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 1 (100.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory tract congestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 1 | 0 | 1 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delusion | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Insomnia | | | |
| subjects affected / exposed | 4 / 8 (50.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 2 / 11 (18.18%) |
| occurrences (all) | 3 | 0 | 2 |
| Amylase increased | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 1 / 1 (100.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 1 | 1 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 3 / 11 (27.27%) |
| occurrences (all) | 0 | 0 | 3 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 3 / 11 (27.27%) |
| occurrences (all) | 2 | 0 | 4 |
| Blood creatinine increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 1 / 1 (100.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 2 | 1 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Fall | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular access site oedema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site ulcer | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular access site rash | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac dysfunction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 1 / 1 (100.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholinergic syndrome | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 1 | 0 | 1 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 3 / 8 (37.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |

| | | | |
|---|---|---|---|
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral motor neuropathy | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 4 / 8 (50.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 4 | 0 | 1 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blepharospasm | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photophobia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Photopsia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 3 / 8 (37.50%) | 0 / 1 (0.00%) | 2 / 11 (18.18%) |
| occurrences (all) | 3 | 0 | 3 |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 3 / 11 (27.27%) |
| occurrences (all) | 1 | 0 | 3 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 1 / 1 (100.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 1 | 1 | 1 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal inflammation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anorectal discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 1 | 0 | 1 |
| Anal rash | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Constipation | | | |
| subjects affected / exposed | 4 / 8 (50.00%) | 0 / 1 (0.00%) | 3 / 11 (27.27%) |
| occurrences (all) | 5 | 0 | 5 |
| Colitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Defaecation urgency | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 4 / 8 (50.00%) | 1 / 1 (100.00%) | 3 / 11 (27.27%) |
| occurrences (all) | 5 | 1 | 3 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 1 | 0 | 1 |
| Dyschezia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 1 | 0 | 1 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lip pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 6 / 8 (75.00%) | 0 / 1 (0.00%) | 2 / 11 (18.18%) |
| occurrences (all) | 6 | 0 | 2 |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 0 | 1 |
| Oral dysaesthesia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Toothache | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 1 / 1 (100.00%) | 2 / 11 (18.18%) |
| occurrences (all) | 1 | 1 | 2 |
| Stomatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 0 | 1 |
| Hepatobiliary disorders | | | |
| Hepatic pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Alopecia | | | |
| subjects affected / exposed | 5 / 8 (62.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 3 / 8 (37.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Dry skin | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail ridging | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail discolouration | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 0 | 1 |

| | | | |
|---|---|---|---|
| Rash maculo-papular | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hyperpigmentation | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Xeroderma | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Bladder pain | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chromaturia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hydronephrosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Pollakiuria | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proteinuria | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 2 |
| Back pain | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 2 | 0 | 1 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Musculoskeletal pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle spasms | | | |
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Anorectal infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Enterobacter infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pneumonia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyuria | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 3 / 8 (37.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 3 | 0 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Gout | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 3 / 8 (37.50%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 3 | 0 | 1 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperphosphataemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 8 (12.50%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyponatraemia | | | |
| subjects affected / exposed | 2 / 8 (25.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 1 / 11 (9.09%) |
| occurrences (all) | 0 | 0 | 2 |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 8 (0.00%) | 0 / 1 (0.00%) | 0 / 11 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | P1 2/3L CRC MSS/BMS300QD + NIVO | P1 2/3L CRC MSS/BMS600QD + NIVO | P1 2/3L CRC MSS/BMS300BID + NIVO |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 7 (100.00%) | 7 / 7 (100.00%) | 8 / 8 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Embolism | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 2 | 1 | 1 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymphorrhoea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Superficial vein thrombosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 3 / 7 (42.86%) | 5 / 8 (62.50%) |
| occurrences (all) | 3 | 3 | 5 |
| Cyst | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 2 | 0 | 1 |
| Swelling | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Perineal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scrotal pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 7 (42.86%) | 0 / 7 (0.00%) | 3 / 8 (37.50%) |
| occurrences (all) | 3 | 0 | 3 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 2 / 7 (28.57%) | 2 / 8 (25.00%) |
| occurrences (all) | 1 | 2 | 2 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal inflammation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delusion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 1 | 0 | 2 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 2 | 1 | 1 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutrophil count decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Contusion | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site oedema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site ulcer | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular access site pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site rash | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac dysfunction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholinergic syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 2 | 0 | 1 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 2 / 7 (28.57%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 1 | 3 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral motor neuropathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Anaemia | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 3 / 7 (42.86%) | 4 / 8 (50.00%) |
| occurrences (all) | 2 | 3 | 8 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blepharospasm | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photophobia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photopsia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 0 | 2 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 2 / 8 (25.00%) |
| occurrences (all) | 1 | 0 | 4 |

| | | | |
|---|---|---|---|
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Anal inflammation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anorectal discomfort | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal rash | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 3 | 1 | 1 |
| Colitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Defaecation urgency | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 7 (42.86%) | 1 / 7 (14.29%) | 3 / 8 (37.50%) |
| occurrences (all) | 3 | 2 | 3 |
| Dry mouth | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 1 | 0 | 1 |
| Dyschezia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 4 / 7 (57.14%) | 1 / 7 (14.29%) | 2 / 8 (25.00%) |
| occurrences (all) | 5 | 1 | 2 |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral dysaesthesia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 5 / 7 (71.43%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 7 | 3 | 1 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hepatobiliary disorders | | | |
| Hepatic pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail ridging | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail discolouration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hyperpigmentation | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Xeroderma | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Bladder pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Chromaturia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proteinuria | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Back pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Flank pain | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Anorectal infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobacter infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyuria | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 2 | 1 | 1 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Viral infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Gout | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 2 / 7 (28.57%) | 2 / 7 (28.57%) | 4 / 8 (50.00%) |
| occurrences (all) | 2 | 2 | 6 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 1 / 7 (14.29%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoalbuminaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 0 | 1 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 2 / 8 (25.00%) |
| occurrences (all) | 0 | 1 | 2 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperphosphataemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 2 | 1 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 1 / 8 (12.50%) |
| occurrences (all) | 0 | 1 | 2 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 0 / 7 (0.00%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 7 (0.00%) | 1 / 7 (14.29%) | 0 / 8 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| **Non-serious adverse events** | P1 2L PC/BMS600QD + NIVO | P2 1L PC/BMS300BID + GEM/NAB + NIVO | P2 1L PC/BMS300BID + GEM/NAB |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 2 / 2 (100.00%) | 34 / 35 (97.14%) | 35 / 35 (100.00%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |

| | | | |
|---|---|---|---|
| Tumour pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 3 | 1 |
| Embolism | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 2 |
| Flushing | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 4 | 6 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 3 | 7 |
| Lymphorrhoea | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Superficial vein thrombosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 5 / 35 (14.29%) |
| occurrences (all) | 0 | 13 | 6 |
| Chest discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 27 / 35 (77.14%) | 23 / 35 (65.71%) |
| occurrences (all) | 1 | 30 | 34 |
| Cyst | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 35 (14.29%) | 6 / 35 (17.14%) |
| occurrences (all) | 0 | 6 | 9 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 2 | 1 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 1 | 1 |
| Malaise | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 2 | 2 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 2 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 12 / 35 (34.29%) | 15 / 35 (42.86%) |
| occurrences (all) | 1 | 12 | 17 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 2 | 3 |
| Mucosal inflammation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 3 | 1 |
| Pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 5 / 35 (14.29%) |
| occurrences (all) | 0 | 2 | 5 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 15 / 35 (42.86%) | 11 / 35 (31.43%) |
| occurrences (all) | 0 | 49 | 24 |
| Swelling | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Perineal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scrotal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 9 / 35 (25.71%) | 10 / 35 (28.57%) |
| occurrences (all) | 0 | 9 | 13 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 1 | 0 | 3 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 35 (11.43%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 4 | 5 |
| Cough | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 11 / 35 (31.43%) | 11 / 35 (31.43%) |
| occurrences (all) | 0 | 13 | 15 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 2 | 2 |
| Hiccups | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 2 | 3 |
| Nasal inflammation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 1 | 1 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 1 | 2 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 2 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 2 | 1 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 3 | 1 |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 35 (11.43%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 4 | 1 |
| Sinus congestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 3 | 3 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delusion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 35 (11.43%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 4 | 2 |
| Insomnia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 1 | 4 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 2 | 1 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 3 | 5 |
| Alanine aminotransferase increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 10 / 35 (28.57%) | 10 / 35 (28.57%) |
| occurrences (all) | 0 | 16 | 23 |
| Amylase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 1 | 6 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 5 / 35 (14.29%) |
| occurrences (all) | 0 | 3 | 7 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 8 / 35 (22.86%) | 8 / 35 (22.86%) |
| occurrences (all) | 0 | 15 | 19 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 10 / 35 (28.57%) | 9 / 35 (25.71%) |
| occurrences (all) | 0 | 17 | 13 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 2 | 4 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 3 | 3 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 35 (17.14%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 7 | 12 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 35 (11.43%) | 5 / 35 (14.29%) |
| occurrences (all) | 0 | 12 | 13 |
| Weight decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 9 / 35 (25.71%) | 7 / 35 (20.00%) |
| occurrences (all) | 0 | 9 | 7 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 3 |
| Platelet count decreased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 7 / 35 (20.00%) | 8 / 35 (22.86%) |
| occurrences (all) | 0 | 10 | 23 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 10 / 35 (28.57%) | 7 / 35 (20.00%) |
| occurrences (all) | 0 | 17 | 12 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 8 / 35 (22.86%) | 9 / 35 (25.71%) |
| occurrences (all) | 0 | 13 | 13 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 3 | 3 |
| Contusion | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 2 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 2 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site oedema | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site ulcer | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Vascular access site rash | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac dysfunction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebellar infarction | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cholinergic syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 35 (14.29%) | 8 / 35 (22.86%) |
| occurrences (all) | 0 | 6 | 8 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 35 (17.14%) | 9 / 35 (25.71%) |
| occurrences (all) | 0 | 7 | 15 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 9 / 35 (25.71%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 12 | 6 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 35 (17.14%) | 6 / 35 (17.14%) |
| occurrences (all) | 0 | 6 | 7 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 2 | 6 |
| Peripheral motor neuropathy | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 0 | 3 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Peripheral sensory neuropathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 11 / 35 (31.43%) | 17 / 35 (48.57%) |
| occurrences (all) | 0 | 12 | 21 |
| Tremor | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 0 | 4 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 20 / 35 (57.14%) | 21 / 35 (60.00%) |
| occurrences (all) | 0 | 28 | 34 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 6 / 35 (17.14%) |
| occurrences (all) | 0 | 5 | 21 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 35 (11.43%) | 5 / 35 (14.29%) |
| occurrences (all) | 0 | 16 | 20 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 7 / 35 (20.00%) | 8 / 35 (22.86%) |
| occurrences (all) | 0 | 8 | 17 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 12 / 35 (34.29%) | 9 / 35 (25.71%) |
| occurrences (all) | 0 | 24 | 26 |

| | | | |
|---|---|---|---|
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blepharospasm | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photophobia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photopsia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 3 | 2 |
| Vitreous floaters | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 9 / 35 (25.71%) | 13 / 35 (37.14%) |
| occurrences (all) | 0 | 12 | 16 |
| Abdominal distension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 3 | 5 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal inflammation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anorectal discomfort | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal rash | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 15 / 35 (42.86%) | 16 / 35 (45.71%) |
| occurrences (all) | 1 | 21 | 22 |
| Colitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Defaecation urgency | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 19 / 35 (54.29%) | 15 / 35 (42.86%) |
| occurrences (all) | 0 | 30 | 29 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 35 (17.14%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 7 | 1 |
| Dyschezia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 3 / 35 (8.57%) | 4 / 35 (11.43%) |
| occurrences (all) | 1 | 4 | 4 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Eructation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 3 | 1 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 1 | 1 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 1 | 1 |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Lip pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 21 / 35 (60.00%) | 23 / 35 (65.71%) |
| occurrences (all) | 1 | 26 | 34 |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral dysaesthesia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 2 | 2 |
| Toothache | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 2 (50.00%) | 11 / 35 (31.43%) | 10 / 35 (28.57%) |
| occurrences (all) | 3 | 14 | 13 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 7 / 35 (20.00%) | 7 / 35 (20.00%) |
| occurrences (all) | 0 | 8 | 10 |
| Hepatobiliary disorders | | | |
| Hepatic pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 11 / 35 (31.43%) | 13 / 35 (37.14%) |
| occurrences (all) | 0 | 11 | 16 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 3 | 1 |
| Dry skin | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 2 | 4 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail ridging | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail discolouration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 2 | 2 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pain of skin | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 13 / 35 (37.14%) | 9 / 35 (25.71%) |
| occurrences (all) | 0 | 22 | 9 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 35 (14.29%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 6 | 3 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 8 / 35 (22.86%) | 7 / 35 (20.00%) |
| occurrences (all) | 0 | 10 | 11 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hyperpigmentation | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 0 | 3 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Xeroderma | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Renal and urinary disorders | | | |
| Bladder pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Chromaturia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 3 | 3 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 2 | 4 |
| Proteinuria | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 35 (14.29%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 5 | 1 |
| Hyperthyroidism | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 35 (17.14%) | 6 / 35 (17.14%) |
| occurrences (all) | 0 | 6 | 6 |
| Back pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 8 / 35 (22.86%) |
| occurrences (all) | 0 | 3 | 9 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 1 | 4 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 4 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 3 | 1 |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 1 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 35 (11.43%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 5 | 7 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain in extremity | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 2 | 5 |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Anorectal infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 3 / 35 (8.57%) |
| occurrences (all) | 0 | 1 | 3 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 0 | 1 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobacter infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 3 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 1 | 2 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 3 | 2 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 2 | 1 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 2 |
| Pyuria | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 3 | 2 |

| | | | |
|---|---|---|---|
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 1 | 1 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 3 / 35 (8.57%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Metabolism and nutrition disorders | | | |
| Gout | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 2 | 11 |
| Decreased appetite | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 16 / 35 (45.71%) | 17 / 35 (48.57%) |
| occurrences (all) | 0 | 19 | 24 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 5 | 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 1 / 35 (2.86%) |
| occurrences (all) | 0 | 2 | 1 |
| Hyperkalaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 2 / 35 (5.71%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 2 | 4 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 35 (14.29%) | 9 / 35 (25.71%) |
| occurrences (all) | 0 | 19 | 24 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 6 / 35 (17.14%) | 6 / 35 (17.14%) |
| occurrences (all) | 0 | 9 | 11 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 8 / 35 (22.86%) | 10 / 35 (28.57%) |
| occurrences (all) | 0 | 10 | 20 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 1 / 35 (2.86%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 2 / 35 (5.71%) |
| occurrences (all) | 0 | 0 | 2 |
| Hyperphosphataemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 5 / 35 (14.29%) | 5 / 35 (14.29%) |
| occurrences (all) | 0 | 15 | 7 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 8 / 35 (22.86%) | 5 / 35 (14.29%) |
| occurrences (all) | 0 | 15 | 11 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 4 / 35 (11.43%) | 4 / 35 (11.43%) |
| occurrences (all) | 0 | 5 | 7 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 7 / 35 (20.00%) | 6 / 35 (17.14%) |
| occurrences (all) | 0 | 16 | 17 |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2 (0.00%) | 0 / 35 (0.00%) | 0 / 35 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | P2 2L CRC/FOLFIRI | P2 2L CRC/BMS300BID + FOLFIRI | P2 2L CRC/BMS150QD + FOLFIRI |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 16 / 17 (94.12%) | 32 / 32 (100.00%) | 31 / 32 (96.88%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 2 | 1 |
| Embolism | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 1 | 2 |
| Hypotension | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Lymphorrhoea | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Superficial vein thrombosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 3 / 17 (17.65%) | 4 / 32 (12.50%) | 3 / 32 (9.38%) |
| occurrences (all) | 18 | 19 | 12 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 10 / 17 (58.82%) | 13 / 32 (40.63%) | 11 / 32 (34.38%) |
| occurrences (all) | 12 | 15 | 18 |
| Cyst | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 3 / 32 (9.38%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 4 | 1 |
| Chest pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 0 | 1 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 0 | 1 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gait disturbance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 1 | 1 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 3 / 32 (9.38%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 3 | 2 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 4 / 17 (23.53%) | 2 / 32 (6.25%) | 5 / 32 (15.63%) |
| occurrences (all) | 4 | 3 | 10 |
| Pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 2 | 2 |
| Peripheral swelling | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 5 / 32 (15.63%) | 4 / 32 (12.50%) |
| occurrences (all) | 1 | 5 | 4 |
| Swelling | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Reproductive system and breast disorders | | | |
| Perineal pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scrotal pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 3 / 17 (17.65%) | 4 / 32 (12.50%) | 7 / 32 (21.88%) |
| occurrences (all) | 3 | 4 | 8 |
| Cough | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 3 / 32 (9.38%) | 4 / 32 (12.50%) |
| occurrences (all) | 1 | 5 | 4 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hiccups | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 17 (11.76%) | 3 / 32 (9.38%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal inflammation | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 2 / 32 (6.25%) |
| occurrences (all) | 1 | 1 | 2 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 2 / 32 (6.25%) |
| occurrences (all) | 1 | 2 | 2 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 2 / 32 (6.25%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 2 | 1 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delirium | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Delusion | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 4 / 32 (12.50%) | 5 / 32 (15.63%) |
| occurrences (all) | 2 | 4 | 6 |
| Sleep disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 3 / 32 (9.38%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Amylase increased | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 2 / 32 (6.25%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 3 / 32 (9.38%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 2 | 1 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 4 / 32 (12.50%) |
| occurrences (all) | 0 | 6 | 4 |
| Blood creatinine increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 2 | 1 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| International normalised ratio increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 4 / 32 (12.50%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 16 | 2 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 3 / 32 (9.38%) | 2 / 32 (6.25%) |
| occurrences (all) | 1 | 3 | 2 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 5 / 32 (15.63%) |
| occurrences (all) | 1 | 1 | 6 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 4 / 17 (23.53%) | 14 / 32 (43.75%) | 8 / 32 (25.00%) |
| occurrences (all) | 21 | 17 | 18 |
| Weight increased | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 6 / 32 (18.75%) |
| occurrences (all) | 17 | 1 | 15 |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infusion related reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 2 | 2 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 2 | 1 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site oedema | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stoma site ulcer | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site rash | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac dysfunction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

| | | | |
|---|---|---|---|
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholinergic syndrome | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 3 / 32 (9.38%) | 2 / 32 (6.25%) |
| occurrences (all) | 1 | 3 | 2 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 2 / 32 (6.25%) | 1 / 32 (3.13%) |
| occurrences (all) | 3 | 2 | 1 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 2 / 32 (6.25%) | 3 / 32 (9.38%) |
| occurrences (all) | 1 | 2 | 3 |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 2 / 32 (6.25%) | 3 / 32 (9.38%) |
| occurrences (all) | 1 | 2 | 3 |
| Paraesthesia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral motor neuropathy | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polyneuropathy | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 5 / 32 (15.63%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 5 | 0 |
| Tremor | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 0 | 2 |
| Syncope | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 3 / 17 (17.65%) | 5 / 32 (15.63%) | 5 / 32 (15.63%) |
| occurrences (all) | 6 | 6 | 6 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Leukocytosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 5 / 17 (29.41%) | 8 / 32 (25.00%) | 9 / 32 (28.13%) |
| occurrences (all) | 12 | 9 | 14 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 1 | 5 |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blepharospasm | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Photophobia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photopsia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitreous floaters | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 10 / 32 (31.25%) | 6 / 32 (18.75%) |
| occurrences (all) | 3 | 13 | 7 |
| Abdominal distension | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 3 / 32 (9.38%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 4 / 32 (12.50%) |
| occurrences (all) | 0 | 1 | 5 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal inflammation | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Anorectal discomfort | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal rash | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|---|---|---|---|
| Constipation | | | |
| subjects affected / exposed | 5 / 17 (29.41%) | 13 / 32 (40.63%) | 7 / 32 (21.88%) |
| occurrences (all) | 7 | 15 | 8 |
| Colitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Defaecation urgency | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 9 / 17 (52.94%) | 13 / 32 (40.63%) | 14 / 32 (43.75%) |
| occurrences (all) | 37 | 29 | 24 |
| Dry mouth | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Dyschezia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 2 / 32 (6.25%) | 4 / 32 (12.50%) |
| occurrences (all) | 2 | 3 | 5 |
| Dysphagia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eructation | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 0 | 1 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 2 | 2 |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 2 |
| Lip pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Nausea | | | |
| subjects affected / exposed | 8 / 17 (47.06%) | 12 / 32 (37.50%) | 12 / 32 (37.50%) |
| occurrences (all) | 16 | 19 | 17 |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral dysaesthesia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Vomiting | | | |
| subjects affected / exposed | 6 / 17 (35.29%) | 6 / 32 (18.75%) | 10 / 32 (31.25%) |
| occurrences (all) | 12 | 7 | 17 |
| Stomatitis | | | |
| subjects affected / exposed | 4 / 17 (23.53%) | 1 / 32 (3.13%) | 7 / 32 (21.88%) |
| occurrences (all) | 36 | 1 | 10 |
| Hepatobiliary disorders | | | |
| Hepatic pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 3 / 17 (17.65%) | 10 / 32 (31.25%) | 7 / 32 (21.88%) |
| occurrences (all) | 3 | 10 | 7 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 1 | 1 |
| Dry skin | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 1 / 32 (3.13%) | 3 / 32 (9.38%) |
| occurrences (all) | 2 | 1 | 3 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 3 / 32 (9.38%) | 3 / 32 (9.38%) |
| occurrences (all) | 0 | 3 | 4 |
| Erythema | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail ridging | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail discolouration | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Night sweats | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 2 | 1 | 2 |
| Pruritus | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 3 / 32 (9.38%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Rash maculo-papular | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin hyperpigmentation | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin discolouration | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Xeroderma | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Bladder pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |
| Chromaturia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 2 |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Proteinuria | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Back pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 4 / 32 (12.50%) | 5 / 32 (15.63%) |
| occurrences (all) | 1 | 4 | 5 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Muscle spasms | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 0 | 2 |
| Pain in extremity | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 5 / 32 (15.63%) | 0 / 32 (0.00%) |
| occurrences (all) | 3 | 5 | 0 |
| Tendonitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Infections and infestations | | | |
| Anorectal infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |

| | | | |
|---|---|---|---|
| Cystitis | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobacter infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 3 / 32 (9.38%) |
| occurrences (all) | 0 | 2 | 4 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Rash pustular | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyuria | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 3 / 32 (9.38%) | 3 / 32 (9.38%) |
| occurrences (all) | 2 | 3 | 3 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 2 / 32 (6.25%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 2 | 1 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Gout | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 3 / 17 (17.65%) | 5 / 32 (15.63%) | 2 / 32 (6.25%) |
| occurrences (all) | 3 | 9 | 2 |
| Decreased appetite | | | |
| subjects affected / exposed | 3 / 17 (17.65%) | 10 / 32 (31.25%) | 6 / 32 (18.75%) |
| occurrences (all) | 5 | 21 | 9 |
| Hypercalcaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 1 / 32 (3.13%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 1 | 2 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 4 / 32 (12.50%) | 0 / 32 (0.00%) |
| occurrences (all) | 2 | 9 | 0 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 1 | 0 | 2 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hyperphosphataemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 2 / 32 (6.25%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 2 | 1 |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 3 / 32 (9.38%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Hypomagnesaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 17 (5.88%) | 5 / 32 (15.63%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 11 | 0 |
| Hypokalaemia | | | |
| subjects affected / exposed | 2 / 17 (11.76%) | 5 / 32 (15.63%) | 1 / 32 (3.13%) |
| occurrences (all) | 3 | 8 | 3 |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 17 (0.00%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 1 / 17 (5.88%) | 0 / 32 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| **Non-serious adverse events** | P2 1L PC/GEM/NAB | P2 2/3L CRC MSS /BMS300BID + NIVO | P2 2L PC/BMS300BID + NIVO |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 31 / 32 (96.88%) | 22 / 24 (91.67%) | 19 / 24 (79.17%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Embolism | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flushing | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 4 / 32 (12.50%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Hypotension | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 32 (12.50%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 4 | 0 | 1 |
| Lymphorrhoea | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Superficial vein thrombosis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 0 | 1 |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 19 / 32 (59.38%) | 8 / 24 (33.33%) | 10 / 24 (41.67%) |
| occurrences (all) | 24 | 9 | 10 |
| Cyst | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 3 | 0 | 1 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Localised oedema | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Influenza like illness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Generalised oedema | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 2 |
| Gait disturbance | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Oedema peripheral | | | |
| subjects affected / exposed | 11 / 32 (34.38%) | 1 / 24 (4.17%) | 2 / 24 (8.33%) |
| occurrences (all) | 11 | 1 | 2 |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 1 | 1 |
| Mucosal inflammation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 1 | 2 |
| Peripheral swelling | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 10 / 32 (31.25%) | 4 / 24 (16.67%) | 5 / 24 (20.83%) |
| occurrences (all) | 13 | 6 | 6 |
| Swelling | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Perineal pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pelvic pain | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Breast pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scrotal pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspnoea | | | |
| subjects affected / exposed | 6 / 32 (18.75%) | 1 / 24 (4.17%) | 3 / 24 (12.50%) |
| occurrences (all) | 7 | 1 | 3 |
| Dyspnoea exertional | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 1 | 3 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 32 (9.38%) | 4 / 24 (16.67%) | 1 / 24 (4.17%) |
| occurrences (all) | 3 | 4 | 1 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 1 |
| Hiccups | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Nasal inflammation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pleural effusion | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Pleuritic pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Productive cough | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Respiratory tract congestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 4 / 24 (16.67%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 4 | 1 |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Confusional state | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Delirium | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Delusion | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 32 (9.38%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 2 / 24 (8.33%) | 3 / 24 (12.50%) |
| occurrences (all) | 1 | 2 | 3 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 10 / 32 (31.25%) | 2 / 24 (8.33%) | 3 / 24 (12.50%) |
| occurrences (all) | 14 | 2 | 3 |
| Amylase increased | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 4 / 32 (12.50%) | 2 / 24 (8.33%) | 5 / 24 (20.83%) |
| occurrences (all) | 7 | 2 | 9 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 9 / 32 (28.13%) | 6 / 24 (25.00%) | 3 / 24 (12.50%) |
| occurrences (all) | 18 | 6 | 4 |
| Blood alkaline phosphatase increased | | | |
| subjects affected / exposed | 9 / 32 (28.13%) | 5 / 24 (20.83%) | 7 / 24 (29.17%) |
| occurrences (all) | 14 | 5 | 9 |
| Blood creatinine increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 2 | 0 | 1 |
| Electrocardiogram QT prolonged | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| International normalised ratio increased | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 3 / 24 (12.50%) |
| occurrences (all) | 1 | 0 | 3 |
| Lipase increased | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Lymphocyte count decreased | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 2 / 24 (8.33%) | 4 / 24 (16.67%) |
| occurrences (all) | 5 | 2 | 4 |
| Weight decreased | | | |
| subjects affected / exposed | 5 / 32 (15.63%) | 4 / 24 (16.67%) | 5 / 24 (20.83%) |
| occurrences (all) | 5 | 4 | 5 |
| Transaminases increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Platelet count decreased | | | |
| subjects affected / exposed | 9 / 32 (28.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 14 | 0 | 4 |
| Neutrophil count decreased | | | |
| subjects affected / exposed | 15 / 32 (46.88%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 31 | 1 | 0 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| White blood cell count decreased | | | |
| subjects affected / exposed | 6 / 32 (18.75%) | 2 / 24 (8.33%) | 2 / 24 (8.33%) |
| occurrences (all) | 9 | 2 | 3 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Fall | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infusion related reaction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 3 |
| Procedural pain | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 3 / 24 (12.50%) |
| occurrences (all) | 1 | 0 | 3 |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site oedema | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stoma site ulcer | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular access site rash | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cardiac dysfunction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palpitations | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinus tachycardia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 1 | 1 |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cholinergic syndrome | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dysgeusia | | | |
| subjects affected / exposed | 5 / 32 (15.63%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 5 | 0 | 1 |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 7 / 32 (21.88%) | 4 / 24 (16.67%) | 0 / 24 (0.00%) |
| occurrences (all) | 7 | 4 | 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 3 / 24 (12.50%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |

| | | | |
|---|---|---|---|
| Neuropathy peripheral | | | |
| subjects affected / exposed | 5 / 32 (15.63%) | 3 / 24 (12.50%) | 3 / 24 (12.50%) |
| occurrences (all) | 5 | 3 | 4 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 1 |
| Peripheral motor neuropathy | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Polyneuropathy | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 8 / 32 (25.00%) | 0 / 24 (0.00%) | 4 / 24 (16.67%) |
| occurrences (all) | 8 | 0 | 4 |
| Tremor | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 1 |
| Syncope | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 20 / 32 (62.50%) | 4 / 24 (16.67%) | 7 / 24 (29.17%) |
| occurrences (all) | 29 | 5 | 8 |
| Febrile neutropenia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cytopenia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphopenia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 4 / 32 (12.50%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Leukocytosis | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 7 / 32 (21.88%) | 2 / 24 (8.33%) | 0 / 24 (0.00%) |
| occurrences (all) | 11 | 2 | 0 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 6 / 32 (18.75%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 21 | 0 | 1 |
| Eye disorders | | | |
| Cataract | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blepharospasm | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dry eye | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photophobia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Photopsia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 1 |
| Vitreous floaters | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 8 / 32 (25.00%) | 6 / 24 (25.00%) | 5 / 24 (20.83%) |
| occurrences (all) | 9 | 7 | 6 |
| Abdominal distension | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 1 / 24 (4.17%) | 4 / 24 (16.67%) |
| occurrences (all) | 2 | 1 | 5 |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 3 / 24 (12.50%) |
| occurrences (all) | 2 | 0 | 3 |
| Anal haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal inflammation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anorectal discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anal rash | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ascites | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Constipation | | | |
| subjects affected / exposed | 12 / 32 (37.50%) | 2 / 24 (8.33%) | 4 / 24 (16.67%) |
| occurrences (all) | 15 | 2 | 4 |
| Colitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Defaecation urgency | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 13 / 32 (40.63%) | 7 / 24 (29.17%) | 6 / 24 (25.00%) |
| occurrences (all) | 16 | 12 | 8 |
| Dry mouth | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 2 | 0 | 1 |
| Dyschezia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Dysphagia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 0 | 1 |
| Eructation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 2 / 24 (8.33%) | 3 / 24 (12.50%) |
| occurrences (all) | 0 | 2 | 3 |
| Faeces discoloured | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gingival bleeding | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematochezia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 0 | 1 |
| Large intestinal haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ileus | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypoaesthesia oral | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Melaena | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 2 | 0 | 1 |
| Mouth ulceration | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 14 / 32 (43.75%) | 5 / 24 (20.83%) | 9 / 24 (37.50%) |
| occurrences (all) | 20 | 6 | 9 |
| Oesophageal spasm | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Proctalgia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral dysaesthesia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 1 |
| Toothache | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 9 / 32 (28.13%) | 0 / 24 (0.00%) | 5 / 24 (20.83%) |
| occurrences (all) | 11 | 0 | 5 |
| Stomatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 32 (18.75%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 6 | 1 | 0 |
| Hepatobiliary disorders | | | |
| Hepatic pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypertransaminasaemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Portal hypertension | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Acne | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Alopecia | | | |
| subjects affected / exposed | 12 / 32 (37.50%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 12 | 0 | 1 |
| Dermatitis acneiform | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 2 / 24 (8.33%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 2 | 1 |
| Dry skin | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Hyperhidrosis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail ridging | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail disorder | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nail discolouration | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Night sweats | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Petechiae | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Palmar-plantar erythrodysaesthesia syndrome | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain of skin | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Onycholysis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Photosensitivity reaction | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash erythematous | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 4 / 24 (16.67%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 4 | 0 |

| | | | |
|---|---|---|---|
| Rash maculo-papular | | | |
| subjects affected / exposed | 4 / 32 (12.50%) | 2 / 24 (8.33%) | 0 / 24 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin hyperpigmentation | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin discolouration | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rash pruritic | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Xeroderma | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Renal and urinary disorders | | | |
| Bladder pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Acute kidney injury | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Chromaturia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Dysuria | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Haematuria | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 0 | 1 |
| Hydronephrosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Proteinuria | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary incontinence | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 1 | 1 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 5 / 32 (15.63%) | 3 / 24 (12.50%) | 1 / 24 (4.17%) |
| occurrences (all) | 5 | 3 | 1 |
| Back pain | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 2 / 24 (8.33%) | 2 / 24 (8.33%) |
| occurrences (all) | 2 | 2 | 2 |
| Bone pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 1 | 1 | 1 |
| Muscle spasms | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 3 / 24 (12.50%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 0 | 1 | 1 |
| Pain in extremity | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Anorectal infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Campylobacter gastroenteritis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Escherichia bacteraemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobacter infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Mucosal infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pneumonia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyuria | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Gout | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 3 / 32 (9.38%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Decreased appetite | | | |
| subjects affected / exposed | 12 / 32 (37.50%) | 7 / 24 (29.17%) | 7 / 24 (29.17%) |
| occurrences (all) | 14 | 7 | 7 |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperkalaemia | | | |
| subjects affected / exposed | 2 / 32 (6.25%) | 1 / 24 (4.17%) | 2 / 24 (8.33%) |
| occurrences (all) | 2 | 1 | 2 |
| Hyperglycaemia | | | |
| subjects affected / exposed | 5 / 32 (15.63%) | 3 / 24 (12.50%) | 7 / 24 (29.17%) |
| occurrences (all) | 10 | 8 | 11 |
| Hypocalcaemia | | | |
| subjects affected / exposed | 7 / 32 (21.88%) | 1 / 24 (4.17%) | 2 / 24 (8.33%) |
| occurrences (all) | 10 | 1 | 3 |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 6 / 32 (18.75%) | 1 / 24 (4.17%) | 5 / 24 (20.83%) |
| occurrences (all) | 7 | 1 | 5 |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 32 (3.13%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 1 / 24 (4.17%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Hyperphosphataemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypophosphataemia | | | |
| subjects affected / exposed | 5 / 32 (15.63%) | 1 / 24 (4.17%) | 1 / 24 (4.17%) |
| occurrences (all) | 7 | 1 | 1 |
| Hyponatraemia | | | |
| subjects affected / exposed | 7 / 32 (21.88%) | 1 / 24 (4.17%) | 2 / 24 (8.33%) |
| occurrences (all) | 10 | 1 | 3 |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 4 / 32 (12.50%) | 0 / 24 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 4 | 0 | 2 |
| Hypokalaemia | | | |
| subjects affected / exposed | 4 / 32 (12.50%) | 0 / 24 (0.00%) | 2 / 24 (8.33%) |
| occurrences (all) | 8 | 0 | 3 |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 32 (0.00%) | 0 / 24 (0.00%) | 0 / 24 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | P2 2L CRC /FOLFIRI P2 2/3L CRC MSS/BMS300BID + NIVO | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 9 / 9 (100.00%) | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Tumour pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular disorders | | | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Embolism | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|---|---|---|---|
| Flushing | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hot flush | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Hypertension | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | |
| occurrences (all) | 2 | | |
| Hypotension | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lymphorrhoea | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Superficial vein thrombosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Venous thrombosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chest discomfort | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fatigue | | | |
| subjects affected / exposed | 5 / 9 (55.56%) | | |
| occurrences (all) | 8 | | |
| Cyst | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chills | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Chest pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Localised oedema | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Influenza like illness | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Generalised oedema | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Malaise | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Gait disturbance | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oedema peripheral | | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | | | |
| occurrences (all) | 4 | | | |
| Non-cardiac chest pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Mucosal inflammation | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Peripheral swelling | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pyrexia | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 9 (22.22%) | | |
| occurrences (all) | 2 | | |
| Swelling | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Temperature intolerance | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Immune system disorders | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Reproductive system and breast disorders | | | |
| Perineal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pelvic pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Breast pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Scrotal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vaginal haemorrhage | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Atelectasis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dyspnoea | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 3 / 9 (33.33%) | | | |
| occurrences (all) | 3 | | | |
| Dyspnoea exertional | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Epistaxis | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Cough | | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | | | |
| occurrences (all) | 3 | | | |
| Dysphonia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hiccups | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Haemoptysis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Nasal congestion | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Nasal inflammation | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pleural effusion | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oropharyngeal pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pleuritic pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Productive cough | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pneumonitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Respiratory tract congestion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Wheezing | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus congestion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Adjustment disorder with depressed mood | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Confusional state | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Delirium | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Delusion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Depression | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Insomnia | | | |
| subjects affected / exposed | 4 / 9 (44.44%) | | |
| occurrences (all) | 5 | | |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Irritability | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Investigations | | | |
| Activated partial thromboplastin time prolonged | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Amylase increased | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | |
| occurrences (all) | 2 | | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 3 | | |
| Blood bilirubin increased | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Aspartate aminotransferase increased | | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | | | |
| occurrences (all) | 3 | | | |
| Blood alkaline phosphatase increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Blood creatinine increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Electrocardiogram QT prolonged | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| International normalised ratio increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Lipase increased | | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | | |
| occurrences (all) | 2 | | | |
| Lymphocyte count decreased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Weight decreased | | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | | |
| occurrences (all) | 2 | | | |
| Transaminases increased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Platelet count decreased | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Neutrophil count decreased | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 4 / 9 (44.44%) | | |
| occurrences (all) | 4 | | |
| Weight increased | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| White blood cell count decreased | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Contusion | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infusion related reaction | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 3 | | |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Post procedural complication | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular access site oedema | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Stoma site ulcer | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular access site pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular access site rash | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Cardiac dysfunction | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Palpitations | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Sinus tachycardia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nervous system disorders | | | |
| Burning sensation | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cerebellar infarction | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cholinergic syndrome | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysgeusia | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | |
| occurrences (all) | 2 | | |
| Dysaesthesia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dizziness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle contractions involuntary | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Headache | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Neuropathy peripheral | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral motor neuropathy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Restless legs syndrome | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Peripheral sensory neuropathy | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Tremor | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Syncope | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Blood and lymphatic system disorders | | | |

| | | | | |
|---|---|---|---|---|
| Anaemia<br>subjects affected / exposed<br>occurrences (all) | 4 / 9 (44.44%)<br>4 | | | |
| Febrile neutropenia<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | | |
| Cytopenia<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | | |
| Lymphopenia<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | | |
| Leukopenia<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | | | |
| Iron deficiency anaemia<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | | |
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | | |
| Neutropenia<br>subjects affected / exposed<br>occurrences (all) | 2 / 9 (22.22%)<br>2 | | | |
| Thrombocytopenia<br>subjects affected / exposed<br>occurrences (all) | 2 / 9 (22.22%)<br>4 | | | |
| Eye disorders<br>Cataract<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | | |
| Blepharospasm<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | | |
| Dry eye | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Eye irritation | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Lacrimation increased | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Photophobia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Photopsia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitreous floaters | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Abdominal pain | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | | |
| occurrences (all) | 6 | | |
| Abdominal distension | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal pain lower | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |

| | | | | |
|---|---|---|---|---|
| Anal haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Abdominal tenderness | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Anal inflammation | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Anorectal discomfort | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Anal rash | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Ascites | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 3 | | | |
| Constipation | | | | |
| subjects affected / exposed | 3 / 9 (33.33%) | | | |
| occurrences (all) | 6 | | | |
| Colitis | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Defaecation urgency | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Diarrhoea | | | | |
| subjects affected / exposed | 6 / 9 (66.67%) | | | |
| occurrences (all) | 11 | | | |
| Dry mouth | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Dyschezia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | | |
|---|---|---|---|---|
| Dyspepsia | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Dysphagia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Eructation | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Flatulence | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Faeces discoloured | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Frequent bowel movements | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Gastrooesophageal reflux disease | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Gingival pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Gingival bleeding | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Haematochezia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Haemorrhoids | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Large intestinal haemorrhage | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | | |
|---|---|---|---|---|
| Intestinal obstruction | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Ileus | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Hypoaesthesia oral | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Lip pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Melaena | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Mouth ulceration | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Nausea | | | | |
| subjects affected / exposed | 5 / 9 (55.56%) | | | |
| occurrences (all) | 6 | | | |
| Oesophageal spasm | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oral pain | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Proctalgia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oral dysaesthesia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oesophagitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | |
|---|---|---|---|
| Rectal haemorrhage<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | | |
| Toothache<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | | |
| Vomiting<br>subjects affected / exposed<br>occurrences (all) | 2 / 9 (22.22%)<br>2 | | |
| Stomatitis<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | | |
| Hepatobiliary disorders<br>Hepatic pain<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>2 | | |
| Hypertransaminasaemia<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Portal hypertension<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | | |
| Skin and subcutaneous tissue disorders<br>Acne<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Alopecia<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | | |
| Dermatitis acneiform<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Dry skin<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>1 | | |
| Hyperhidrosis | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Erythema | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Ecchymosis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Nail ridging | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Nail disorder | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Nail discolouration | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Night sweats | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Petechiae | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Palmar-plantar erythrodysaesthesia syndrome | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Pain of skin | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Onycholysis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Photosensitivity reaction | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | |
|---|---|---|---|
| Rash erythematous<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Rash<br>subjects affected / exposed<br>occurrences (all) | 1 / 9 (11.11%)<br>2 | | |
| Pruritus<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Rash maculo-papular<br>subjects affected / exposed<br>occurrences (all) | 2 / 9 (22.22%)<br>2 | | |
| Rash papular<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Skin hyperpigmentation<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Skin discolouration<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Rash pruritic<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Xeroderma<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Renal and urinary disorders<br>Bladder pain<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Acute kidney injury<br>subjects affected / exposed<br>occurrences (all) | 0 / 9 (0.00%)<br>0 | | |
| Chromaturia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dysuria | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haematuria | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hydronephrosis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pollakiuria | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Proteinuria | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary incontinence | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Urinary tract obstruction | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Endocrine disorders | | | |
| Hypothyroidism | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperthyroidism | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Back pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 9 (33.33%) | | |
| occurrences (all) | 4 | | |
| Bone pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle spasms | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Myalgia | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | |
| occurrences (all) | 2 | | |
| Neck pain | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Tendonitis | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Infections and infestations | | | |
| Anorectal infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | | |
|---|---|---|---|---|
| Bacteraemia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Bronchitis | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| COVID-19 | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Campylobacter gastroenteritis | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Cellulitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Conjunctivitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Cystitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Diverticulitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Fungal infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Escherichia bacteraemia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Enterobacter infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Oral candidiasis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | | |
|---|---|---|---|---|
| Nasopharyngitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Mucosal infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Paronychia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Rhinitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Rash pustular | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Pyuria | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Urinary tract infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Upper respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |
| Sepsis | | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | | |
| occurrences (all) | 1 | | | |
| Sinusitis | | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | | |
| occurrences (all) | 0 | | | |

| | | | |
|---|---|---|---|
| Viral infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vascular device infection | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Metabolism and nutrition disorders | | | |
| Gout | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Decreased appetite | | | |
| subjects affected / exposed | 4 / 9 (44.44%) | | |
| occurrences (all) | 4 | | |
| Hypercalcaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypernatraemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypermagnesaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 2 | | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 2 | | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypoalbuminaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Hyperuricaemia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hyperphosphataemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypophosphataemia | | | |
| subjects affected / exposed | 1 / 9 (11.11%) | | |
| occurrences (all) | 1 | | |
| Hyponatraemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypomagnesaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypokalaemia | | | |
| subjects affected / exposed | 2 / 9 (22.22%) | | |
| occurrences (all) | 2 | | |
| Hypovolaemia | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 0 / 9 (0.00%) | | |
| occurrences (all) | 0 | | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 11 May 2017 | Original protocol |
| 28 June 2017 | Number of patients in each cohort specified in Part 1 and 2. The sample sizes for cohorts in Part 2 are based on the number of evaluable participants needed to support a decision whether or not a treatment is effective using target and historic response rates, while controlling Type 1 error. Clarification in response to FDA feedback. Inclusion criteria to ensure that patients received appropriate prior therapy. Inclusion criteria was modified to ensure that participants received appropriate prior therapy. Inclusion criteria was modified to ensure that participants received appropriate prior therapy. Grade 4 laboratory abnormalities will be considered DLT. Administration of biologics was updated to acknowledge different local standard of care practices. Safety stopping rules added for Part 2 of the study. List of clinical laboratory assessments updated to align with hepatitis C testing described in exclusion criteria. PBMC sample collections are not needed. Correction of error in Table for Arm A. |
| 11 September 2017 | Overall survival is being added as an exploratory endpoint as a direct measure of clinical benefit. In response to health authority feedback, pharmacokinetics (PK) samples will be collected to assess the potential for a drug-drug interaction. A Survival Follow-up period was added to the study design and Schedule of Activities to assess the clinical benefit of study treatments. In response to health authority feedback, PK samples will be collected to assess the potential for a drug-drug interaction. Collection of plasma ctDNA for analysis will enable assessments of tumor mutations, tumor mutation burden, and other biomarkers. Overall survival is being added as an exploratory endpoint as a direct measure of clinical benefit. List of clinical laboratory assessments updated to align with amylase testing described in Nonhepatic Nonhematologic DLT [Section 7.4.1, 3), a), v), (3)] and Guidelines for Permanent Discontinuation in Nivolumab (Arm C) [Section 7.4.7.3, 7), d)]. |
| 07 May 2018 | -Randomization was added to Part 2 to better evaluate safety and efficacy of the BMS-813160 + chemotherapy combination.<br>A second dose was added to Arm A to test PK, PD, and efficacy of lower dose of BMS-813160 in combination with chemotherapy.<br>- Randomization was added to Part 2 to better evaluate safety and efficacy of BMS-813160 + chemotherapy +/- nivolumab.<br>A combination of BMS-813160 + nivolumab + Gem/nab-paclitaxel combination was added to Arm B to evaluate safety and preliminary efficacy of the combination. - FOLFIRI retreatment and MSI-H post PD-1 cohorts were removed from the study. Bevacizumab can be added to 2L FOLFIRI treatment if appropriate. A staggered dosing (sentinel participant) approach and safety lead in will reduce the number of patients enrolled to the combination if there are any unanticipated toxicities. Study objectives and endpoints were updated to align with revisions to the Part 2 study design. The exploratory BMS-813160 600 mg BID dosing regimen was not initiated in Part 1 of the study, and this regimen will not be explored in Part 2. Eligible participants on the control arms of Arm A and B will be allowed to cross over at the time of PD as they may be eligible for Arm C. Follow-up period extended to monitor for AEs, accounting for the long half-life of nivolumab. Sections were updated to align with revisions in Part 2 of the study design and Section 10.1, Sample Size Determination. Section 2 timing and events tables were updated to align with revisions in Part 2 of the study design. On-going clinical safety update of BMS-813160 in Part 1 provided. |

| | |
|---|---|
| 12 July 2018 | Table 2-2 and Table 2-7 were added and modified, respectively, to clarify the procedures needed for participants in Part 2 of the study to cross over from Cohorts 1c and 3c to Cohorts 5 and 4, respectively. The study inclusion criteria were reordered to<br>facilitate the transfer of this information in the electronic data capture system (RAVE). An edit check in RAVE will ensure that the site will select the accurate revised new criteria. Table was modified to clarify the biomarker sample collections for cross-over participants. Evolving science indicates that the best collection for the peripheral gene expression profiling<br>analysis is whole blood PAXgene instead of whole blood with isolated PBMC. |
| 12 December 2018 | Short Title added for clarity and alignment with Short Title provided on ClinicalTrials.gov. Clarification of the dose and schedule of BMS-813160 in Part 2 of the study. Clarification of the dose and schedule of BMS-813160 in Part 2 of the study. The phrase in bold was added to clarify the dose and schedule of BMS-813160 in Part 2 of the study. Study formulary updated with the addition of 75-mg and 300-mg BMS-813160 tablets. Statement added based on safety data available from Part 1 of the study. Section updated based on preliminary PK data available from Part 1 of the study. Study formulary updated with the addition of 75-mg and 300-mg BMS-813160 tablets. Rationale for the selection of BMS-813160 300 mg BID dosing regimen for primary investigation in Part 2 of the study. |
| 05 December 2019 | The following key changes were made:<br>- Closed enrollment in Cohort 4 of Part 2.<br>- Removed stratification from the protocol.<br>- Revised time that women of childbearing potential must follow contraception instructions to duration of study therapy plus 10 months. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported