Clinical trial results:
A Phase 1/2 Study of Durvalumab and Monalizumab in Adult Subjects with Select Advanced Solid Tumors

Summary

EudraCT number	2016-000662-38
Trial protocol	GB HU ES FR BE IT
Global end of trial date	26 October 2021

Results information

Result version number	v1
This version publication date	06 November 2022
First version publication date	06 November 2022

Trial information

Trial identification

Sponsor protocol code	D419NC00001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02671435
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	MedImmune, LLC
Sponsor organisation address	One MedImmune Way, Gaithersburg, Maryland, United States, 20878
Public contact	Global Clinical Lead, AstraZeneca Clinical Study Information Center, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca Clinical Study Information Center, +1 877-240-9479, information.center@astrazeneca.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	22 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To assess safety and tolerability, describe dose-limiting toxicities (DLTs), and determine maximum tolerated dose (MTD) of durvalumab in combination with monalizumab in subjects with advanced solid tumors and with select advanced solid tumors.
2. To assess safety and tolerability of durvalumab in combination with monalizumab plus chemotherapy with or without a biologic agent (bevacizumab or cetuximab), in subjects with first line (1L) or second line (2L) MSS-CRC.
3. To assess safety (C1A, C2A) and tolerability (C1A and C2A), and evaluate the preliminary antitumor activity (C1A only) of durvalumab in combination with monalizumab plus cetuximab in subjects with 3L MSS-CRC that is RAS mutant (C1A) or RAS/BRAF wild type (C2A).
4. To assess safety (C1B, C2B) and tolerability (C1B and C2B), and evaluate the preliminary antitumor activity (C1B only) of monalizumab in combination with cetuximab in subjects with 3L MSS-CRC that is RAS mutant (C1B) or RAS/BRAF wild type (C2B).

Protection of trial subjects:

The conduct of this clinical study met all local and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and are consistent with International Conference on Harmonization guideline: Good Clinical Practice, and applicable regulatory requirements. Participants signed an informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 February 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 3
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Canada: 11
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Hungary: 8
Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	New Zealand: 7
Country: Number of subjects enrolled	Korea, Republic of: 40
Country: Number of subjects enrolled	Spain: 62
Country: Number of subjects enrolled	United Kingdom: 16

Country: Number of subjects enrolled	United States: 219
Worldwide total number of subjects	383
EEA total number of subjects	87

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)	268
From 65 to 84 years	115
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at study sites located in North America, Europe, and Asia Pacific, across 47 sites and 11 countries (Australia, Belgium, Canada, France, Hungary, Italy, New Zealand, South Korea, Spain, United Kingdom, and United States).

Pre-assignment

Screening details:

A total of 383 participants were included in this study of which 382 participants received treatment.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva

Arm description:

Participants received intravenous (IV) infusions of durvalumab (Durva) 1500 mg every 4 weeks (Q4W) in combination with monalizumab (Mona) 22.5 mg every 2 weeks (Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed disease progression (PD), or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg every 4 weeks (Q4W) up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 22.5 mg every 2 weeks (Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed disease progression (PD), or documentation of subject withdrawal for another reason.

Arm title	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva

Arm description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 75 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 75 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva

Arm description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 225 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 225 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva

Arm description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva

Arm description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)

Arm description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)

Arm description:

Participants with ovarian cancer received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)

Arm description:

Participants with endometrial MSS received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)

Arm description:

Participants with non-small cell lung cancer (NSCLC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva

Arm description:

Participants with first-line (1L) MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus mFOLFOX (oxaliplatin 85 mg/m^2 IV infusion, folinic acid 400 mg/m^2 infusion, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of bevacizumab (Beva) 5 mg/kg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	mFOLFOX6
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of mFOLFOX (oxaliplatin 85 mg/m^2 IV infusion, folinic acid 400 mg/m^2 infusion, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Bevacizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion

Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of bevacizumab 5 mg/kg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu

Arm description:

Participants with 1L MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W, plus mFOLFOX6 (oxaliplatin 85 mg/m^2, folinic acid 400 mg/m^2, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of cetuximab (Cetu) (loading dose of 400 mg/m^2 on Day 1, followed by maintenance dose of 250 mg/m^2 IV infusion every week starting on Day 8, then changed to 500 mg/m^2 IV infusion Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

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

Dosage and administration details:

Intravenous infusion of cetuximab (loading dose of 400 mg/m^2 on Day 1, followed by maintenance dose of 250 mg/m^2 IV infusion every week starting on Day 8, then changed to 500 mg/m^2 IV infusion Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	mFOLFOX6
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of mFOLFOX (oxaliplatin 85 mg/m^2 IV infusion, folinic acid 400 mg/m^2 infusion, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu

Arm description:

Participants with recurrent or metastatic third-line (3L) RAS mutant MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab

500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

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

Dosage and administration details:

Intravenous infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu

Arm description:

Participants with recurrent or metastatic 3L RAS mutant MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

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

Dosage and administration details:

Intravenous infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu

Arm description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm type	Experimental
Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

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

Dosage and administration details:

Intravenous infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Durvalumab
Investigational medicinal product code	MEDI4736
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of durvalumab 1500 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Arm title	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu

Arm description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

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

Dosage and administration details:

Intravenous infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Investigational medicinal product name	Monalizumab
Investigational medicinal product code	IPH2201
Other name	
Pharmaceutical forms	Powder for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Intravenous infusion of monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity,

documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Number of subjects in period 1	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva
Started	3	3	3
Treated	3	3	3
Completed	0	0	0
Not completed	3	3	3
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	2	-	2
Death	1	3	-
Un-specified	-	-	-
Lost to follow-up	-	-	1

Number of subjects in period 1	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)
Started	18	18	40
Treated	18	18	40
Completed	0	0	0
Not completed	18	18	40
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	2	2	7
Death	15	14	29
Un-specified	-	1	3
Lost to follow-up	-	1	1

Number of subjects in period 1	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)
Started	40	40	20
Treated	40	40	20
Completed	0	0	0
Not completed	40	40	20
Adverse event, serious fatal	-	2	1
Consent withdrawn by subject	2	7	1
Death	34	26	18

Un-specified	2	3	-
Lost to follow-up	2	2	-

Number of subjects in period 1	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Started	18	18	40
Treated	18	18	39
Completed	0	0	0
Not completed	18	18	40
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	2	4
Death	10	8	29
Un-specified	5	8	4
Lost to follow-up	2	-	3

Number of subjects in period 1	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Started	41	44	37
Treated	41	44	37
Completed	0	0	0
Not completed	41	44	37
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	4	4	2
Death	29	29	26
Un-specified	5	9	8
Lost to follow-up	3	2	-

Reporting groups

Reporting group title	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva

Reporting group description:

Participants received intravenous (IV) infusions of durvalumab (Durva) 1500 mg every 4 weeks (Q4W) in combination with monalizumab (Mona) 22.5 mg every 2 weeks (Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed disease progression (PD), or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 75 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 225 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)

Reporting group description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)

Reporting group description:

Participants with ovarian cancer received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)

Reporting group description:

Participants with endometrial MSS received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva

Reporting group description:

Participants with first-line (1L) MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus mFOLFOX (oxaliplatin 85 mg/m^2 IV infusion, folinic acid 400 mg/m^2 infusion, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of bevacizumab (Beva) 5 mg/kg Q2W up to

3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu

Reporting group description:

Participants with 1L MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W, plus mFOLFOX6 (oxaliplatin 85 mg/m^2, folinic acid 400 mg/m^2, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of cetuximab (Cetu) (loading dose of 400 mg/m^2 on Day 1, followed by maintenance dose of 250 mg/m^2 IV infusion every week starting on Day 8, then changed to 500 mg/m^2 IV infusion Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu

Reporting group description:

Participants with recurrent or metastatic third-line (3L) RAS mutant MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS mutant MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva
Number of subjects	3	3	3
Age Categorical			
Intent-to-treat (ITT) population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	1	2	2
>=65 years	2	1	1
Age continuous			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: years			
arithmetic mean	58.0	55.7	59
standard deviation	± 21.7	± 18.0	± 15.1

Sex: Female, Male			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
Female	3	3	2
Male	0	0	1
Race (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	3	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
Hispanic or Latino	1	1	0
Not Hispanic or Latino	2	2	3
Unknown or Not Reported	0	0	0

Reporting group values	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)
Number of subjects	18	18	40
Age Categorical			
Intent-to-treat (ITT) population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	14	10	33
>=65 years	4	8	7
Age continuous			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: years			
arithmetic mean	56.4	60	53.6
standard deviation	± 13.5	± 13.5	± 12.9
Sex: Female, Male			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
Female	17	6	15
Male	1	12	25
Race (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
American Indian or Alaska Native	0	0	0

Asian	1	2	3
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	1	0	1
White	15	15	36
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
Hispanic or Latino	3	0	6
Not Hispanic or Latino	15	17	34
Unknown or Not Reported	0	1	0

Reporting group values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)
Number of subjects	40	40	20
Age Categorical			
Intent-to-treat (ITT) population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	24	21	9
>=65 years	16	19	11
Age continuous			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: years			
arithmetic mean	61.5	63.7	63.2
standard deviation	± 9.1	± 8.1	± 7.9
Sex: Female, Male			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
Female	40	40	6
Male	0	0	14
Race (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	1	2	0
Native Hawaiian or Other Pacific Islander	0	0	1
Black or African American	3	4	1
White	35	30	16
More than one race	0	0	0
Unknown or Not Reported	1	3	2
Ethnicity (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			

Hispanic or Latino	5	3	2
Not Hispanic or Latino	35	37	16
Unknown or Not Reported	0	0	2

Reporting group values	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Number of subjects	18	18	40
Age Categorical			
Intent-to-treat (ITT) population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	10	15	31
>=65 years	8	3	9
Age continuous			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: years			
arithmetic mean	60.8	55.4	55.8
standard deviation	± 9.9	± 9.4	± 10.7
Sex: Female, Male			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
Female	8	8	17
Male	10	10	23
Race (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	4	9
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	2
White	13	13	29
More than one race	0	0	0
Unknown or Not Reported	2	1	0
Ethnicity (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
Hispanic or Latino	1	1	3
Not Hispanic or Latino	17	17	37
Unknown or Not Reported	0	0	0

Reporting group values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Number of subjects	41	44	37

Age Categorical			
Intent-to-treat (ITT) population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	36	33	27
>=65 years	5	11	10
Age continuous			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: years			
arithmetic mean	52.3	55.9	58.8
standard deviation	± 10.6	± 11.3	± 9.6
Sex: Female, Male			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
Female	16	17	18
Male	25	27	19
Race (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	8	14	13
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	1	1	1
White	30	25	22
More than one race	0	1	0
Unknown or Not Reported	2	2	1
Ethnicity (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
Hispanic or Latino	6	4	0
Not Hispanic or Latino	35	40	37
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	383		
Age Categorical			
Intent-to-treat (ITT) population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
<=18 years	0		
Between 18 and 65 years	268		
>=65 years	115		
Age continuous			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: years			
arithmetic mean			
standard deviation	-		

Sex: Female, Male			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Participants			
Female	216		
Male	167		
Race (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	58		
Native Hawaiian or Other Pacific Islander	3		
Black or African American	17		
White	288		
More than one race	1		
Unknown or Not Reported	15		
Ethnicity (NIH/OMB)			
The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.			
Units: Subjects			
Hispanic or Latino	36		
Not Hispanic or Latino	344		
Unknown or Not Reported	3		

End points reporting groups

Reporting group title	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva

Reporting group description:

Participants received intravenous (IV) infusions of durvalumab (Durva) 1500 mg every 4 weeks (Q4W) in combination with monalizumab (Mona) 22.5 mg every 2 weeks (Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed disease progression (PD), or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 75 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 225 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)

Reporting group description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)

Reporting group description:

Participants with ovarian cancer received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)

Reporting group description:

Participants with endometrial MSS received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva

Reporting group description:

Participants with first-line (1L) MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus mFOLFOX (oxaliplatin 85 mg/m^2 IV infusion, folinic acid 400 mg/m^2 infusion, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of bevacizumab (Beva) 5 mg/kg Q2W up to

3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu

Reporting group description:

Participants with 1L MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W, plus mFOLFOX6 (oxaliplatin 85 mg/m^2, folinic acid 400 mg/m^2, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of cetuximab (Cetu) (loading dose of 400 mg/m^2 on Day 1, followed by maintenance dose of 250 mg/m^2 IV infusion every week starting on Day 8, then changed to 500 mg/m^2 IV infusion Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu

Reporting group description:

Participants with recurrent or metastatic third-line (3L) RAS mutant MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS mutant MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Subject analysis set title	Dose-escalation Cohort4+Dose-expansion: Mona 750mg Q2W + Durva
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with solid tumors, microsatellite-stable colorectal cancer (MSS-CRC), ovarian cancer, MSS endometrial cancer or non-small cell lung cancer (NSCLC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Subject analysis set title	Dose-escalation (1-5) + dose-expansion + dose-exploration
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants in dose-escalation cohorts received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 22.5, 75, 225 or 750 mg Q2W (Cohorts 1, 2, 3 and 4) or 750 mg Q4W (Cohort 5), dose-expansion cohorts participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W. Participants with recurrent or metastatic 3L RAS mutant (C1A) or RAS/BRAF wild type (C2A) MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab. Participants with 1L MSS-CRC in Cohorts A1 and A2 received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W, plus mFOLFOX6 Q2W plus either IV infusion of bevacizumab 5 mg/kg Q2W (Cohort A1) or IV infusion of cetuximab (Cohort A2). Participants in all cohorts received treatment up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Subject analysis set title	Exploration Cohorts A2, C1A, C2A, C1B, and C2B
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with recurrent or metastatic 3L RAS mutant (C1A) or RAS/BRAF wild type (C2A) MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15. Participants with recurrent or metastatic 3L RAS mutant (C1B) or RAS/BRAF wild type (C2B) MSS-CRC received IV infusions monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15. Participants with 1L MSS-CRC in Cohort A2 received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W, plus mFOLFOX6 Q2W plus IV infusion of cetuximab (Cohort A2). Participants in all cohorts received treatment up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Primary: Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Treatment Emergent Serious Adverse Events (TESAEs)

End point title	Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Treatment Emergent Serious Adverse Events (TESAEs)[1]

End point description:

An adverse event (AE) is any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. A serious adverse event (SAE) is an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. The TEAEs are defined as events present at baseline that worsened in intensity after administration of study drug or events absent at baseline that emerged after administration of study drug. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Primary

End point timeframe:

Day 1 through 246.9 weeks (maximum observed duration)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: Participants				
Any TEAEs	3	3	3	18
Any TESAEs	1	0	1	8

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: Participants				
Any TEAEs	17	39	40	39
Any TESAEs	4	11	16	17

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	18	39
Units: Participants				
Any TEAEs	20	18	18	39
Any TESAEs	7	10	11	10

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	44	37	
Units: Participants				
Any TEAEs	41	44	36	
Any TESAEs	5	9	11	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

End point title	Change From Baseline in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)[2]

End point description:

Change from baseline in SBP and DBP (minimum post baseline change [PBC] and maximum PBC) are reported. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Primary

End point timeframe:

Day 1 (baseline) through 246.9 weeks (maximum observed duration)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: mmHg				
arithmetic mean (standard deviation)				
SBP min PBC	-19.00 (± 21.63)	-26.00 (± 10.82)	-14.67 (± 11.55)	-22.94 (± 12.73)
SBP max PBC	27.33 (± 5.69)	19.00 (± 5.57)	28.67 (± 20.82)	29.22 (± 15.78)
DBP min PBC	-15.67 (± 18.01)	-22.00 (± 10.00)	-10.67 (± 9.07)	-17.89 (± 9.58)
DBP max PBC	23.67 (± 11.93)	11.67 (± 4.93)	18.00 (± 9.64)	14.06 (± 12.75)

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: mmHg				
arithmetic mean (standard deviation)				
SBP min PBC	-23.06 (± 20.48)	-21.45 (± 12.89)	-22.55 (± 13.35)	-21.23 (± 12.29)
SBP max PBC	22.00 (± 19.16)	21.10 (± 12.04)	22.15 (± 17.39)	23.55 (± 14.13)
DBP min PBC	-18.61 (± 11.05)	-16.60 (± 10.40)	-17.60 (± 9.81)	-13.05 (± 7.21)
DBP max PBC	12.39 (± 9.30)	15.58 (± 9.69)	12.63 (± 11.11)	19.83 (± 10.15)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	18	39
Units: mmHg				
arithmetic mean (standard deviation)				
SBP min PBC	-26.40 (± 12.75)	-29.28 (± 19.19)	-24.61 (± 10.92)	-23.31 (± 12.88)
SBP max PBC	22.95 (± 11.69)	27.17 (± 21.63)	23.61 (± 11.27)	20.74 (± 15.31)
DBP min PBC	-19.15 (± 10.28)	-18.11 (± 8.98)	-20.50 (± 9.79)	-16.13 (± 9.33)

DBP max PBC	16.65 (± 9.46)	18.11 (± 9.33)	14.22 (± 12.18)	13.54 (± 10.01)

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	44	37	
Units: mmHg				
arithmetic mean (standard deviation)				
SBP min PBC	-20.80 (± 11.87)	-25.57 (± 13.99)	-25.05 (± 16.86)	
SBP max PBC	17.20 (± 10.51)	23.00 (± 13.18)	22.59 (± 15.69)	
DBP min PBC	-16.39 (± 9.94)	-18.09 (± 9.69)	-17.68 (± 12.15)	
DBP max PBC	13.10 (± 8.98)	16.05 (± 10.06)	14.43 (± 9.01)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Respiratory Rate (RR)

End point title	Change From Baseline in Respiratory Rate (RR)[3]

End point description:

Change from baseline in RR (minimum PBC and maximum PBC) are reported. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Primary

End point timeframe:

Day 1 (baseline) through 246.9 weeks (maximum observed duration)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: breaths/min				
arithmetic mean (standard deviation)				
RR min PBC	-2.00 (± 2.00)	-3.00 (± 1.00)	-1.33 (± 2.31)	-1.78 (± 1.31)
RR max PBC	2.00 (± 3.46)	2.33 (± 0.58)	2.67 (± 1.15)	1.72 (± 1.49)

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: breaths/min				
arithmetic mean (standard deviation)				
RR min PBC	-1.50 (± 1.86)	-1.93 (± 1.86)	-1.53 (± 1.52)	-1.83 (± 1.62)
RR max PBC	1.83 (± 1.42)	2.40 (± 2.37)	2.53 (± 2.24)	2.40 (± 2.62)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	18	39
Units: breaths/min				
arithmetic mean (standard deviation)				
RR min PBC	-1.55 (± 3.12)	-2.00 (± 1.94)	-1.67 (± 1.78)	-2.15 (± 2.23)
RR max PBC	4.05 (± 3.09)	2.50 (± 2.09)	3.39 (± 3.62)	1.85 (± 1.73)

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	44	37	
Units: breaths/min				
arithmetic mean (standard deviation)				
RR min PBC	-1.59 (± 1.52)	-2.00 (± 1.33)	-1.92 (± 1.89)	
RR max PBC	2.00 (± 1.55)	2.59 (± 1.83)	3.14 (± 4.60)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Pulse Rate (PR)

End point title	Change From Baseline in Pulse Rate (PR)[4]

End point description:

Change from baseline in PR (minimum PBC and maximum PBC) are reported. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Primary

End point timeframe:

Day 1 (baseline) through 246.9 weeks (maximum observed duration)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: beats/min				
arithmetic mean (standard deviation)				
PR min PBC	-5.33 (± 2.52)	-14.33 (± 6.51)	-7.00 (± 1.73)	-15.67 (± 11.83)
PR max PBC	38.33 (± 10.02)	16.67 (± 6.11)	21.67 (± 8.08)	19.33 (± 15.05)

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: beats/min				
arithmetic mean (standard deviation)				
PR min PBC	-15.39 (± 9.20)	-14.70 (± 9.39)	-12.24 (± 10.10)	-11.38 (± 10.98)
PR max PBC	17.78 (± 11.12)	20.28 (± 10.03)	20.68 (± 13.42)	22.60 (± 12.17)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	18	39
Units: beats/min				
arithmetic mean (standard deviation)				

PR min PBC	-13.95 (± 9.12)	-15.67 (± 8.84)	-18.11 (± 11.98)	-15.74 (± 11.20)
PR max PBC	25.80 (± 11.27)	21.28 (± 13.48)	21.06 (± 12.24)	23.54 (± 12.83)

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	44	37	
Units: beats/min				
arithmetic mean (standard deviation)				
PR min PBC	-13.15 (± 11.89)	-13.91 (± 7.04)	-11.68 (± 9.02)	
PR max PBC	23.88 (± 11.31)	25.18 (± 13.71)	27.38 (± 13.92)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Body Temperature (BT)

End point title	Change From Baseline in Body Temperature (BT)[5]

End point description:

Change from baseline in BT (minimum PBC and maximum PBC) are reported. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Primary

End point timeframe:

Day 1 (baseline) through 246.9 weeks (maximum observed duration)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: degree Celsius				
arithmetic mean (standard deviation)				
BT min PBC	-0.30 (± 0.30)	-0.37 (± 0.38)	-0.67 (± 0.55)	-0.66 (± 0.56)
BT max PBC	0.63 (± 0.32)	0.93 (± 0.92)	0.50 (± 0.26)	0.78 (± 0.72)

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: degree Celsius				
arithmetic mean (standard deviation)				
BT min PBC	-0.48 (± 0.28)	-0.62 (± 0.39)	-0.63 (± 0.42)	-0.47 (± 0.32)
BT max PBC	0.60 (± 0.73)	0.65 (± 0.43)	0.64 (± 0.46)	0.77 (± 0.47)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	18	39
Units: degree Celsius				
arithmetic mean (standard deviation)				
BT min PBC	-0.51 (± 0.26)	-0.84 (± 0.46)	-0.79 (± 0.48)	-0.51 (± 0.39)
BT max PBC	0.72 (± 0.46)	0.89 (± 0.51)	0.56 (± 0.43)	0.75 (± 0.57)

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	44	37	
Units: degree Celsius				
arithmetic mean (standard deviation)				
BT min PBC	-0.52 (± 0.33)	-0.65 (± 0.45)	-0.66 (± 0.58)	
BT max PBC	0.70 (± 0.53)	0.91 (± 0.64)	0.81 (± 0.66)	

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Oxygen Saturation (OS)

End point title	Change From Baseline in Oxygen Saturation (OS)[6]

End point description:

Change from baseline in OS (minimum PBC and maximum PBC) are reported. The arbitrary number 99999 signified standard deviation was not reported as only one participant was evaluable for the specified arm group. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Primary

End point timeframe:

Day 1 (baseline) through 246.9 weeks (maximum observed duration)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[7]	0[8]	1
Units: Percentage of oxygen saturation				
arithmetic mean (standard deviation)				
OS min PBC	-1.00 (± 99999)	()	()	-3.00 (± 99999)
OS max PBC	-1.00 (± 99999)	()	()	-3.00 (± 99999)

Notes:

[7] - No participants were analyzed for change in OS.

[8] - No participants were analyzed for change in OS.

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	1	0[9]
Units: Percentage of oxygen saturation				
arithmetic mean (standard deviation)				
OS min PBC	-3.00 (± 99999)	-0.67 (± 1.53)	-21.00 (± 99999)	()
OS max PBC	-3.00 (± 99999)	-0.67 (± 1.53)	-21.00 (± 99999)	()

Notes:

[9] - No participants were analyzed for change in OS.

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	1	0[10]
Units: Percentage of oxygen saturation				

arithmetic mean (standard deviation)				
OS min PBC	0 (± 99999)	0.50 (± 2.12)	-4.00 (± 99999)	()
OS max PBC	0 (± 99999)	0.50 (± 2.12)	-4.00 (± 99999)	()

Notes:

[10] - No participants were analyzed for change in OS.

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	1	6	
Units: Percentage of oxygen saturation				
arithmetic mean (standard deviation)				
OS min PBC	0.50 (± 0.71)	-1.00 (± 99999)	-0.33 (± 2.80)	
OS max PBC	0.50 (± 0.71)	-1.00 (± 99999)	-0.33 (± 2.80)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Notable Change in QTcF and QTcB From Baseline

End point title	Number of Participants With Notable Change in QTcF and QTcB From Baseline[11]

End point description:

Participants who had notable QTcF and QTcB interval change from baseline are reported. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Primary

End point timeframe:

Day 1 (baseline) through 246.9 weeks (maximum observed duration)

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: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	16
Units: Participants				
QTcF>30 msec	0	0	0	2
QTcF>60 msec	0	0	0	1
QTcB>30 msec	1	0	0	3

QTcB>60 msec	0	0	0	1

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	39	38	40
Units: Participants				
QTcF>30 msec	1	6	5	2
QTcF>60 msec	0	0	2	1
QTcB>30 msec	2	5	5	4
QTcB>60 msec	0	1	3	1

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	18	17	39
Units: Participants				
QTcF>30 msec	2	1	2	3
QTcF>60 msec	1	0	0	1
QTcB>30 msec	3	1	6	4
QTcB>60 msec	1	0	0	1

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	43	37	
Units: Participants				
QTcF>30 msec	3	5	5	
QTcF>60 msec	1	0	1	
QTcB>30 msec	8	9	6	
QTcB>60 msec	2	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With at Least 2-Grade Shift From Baseline in Laboratory Parameters

End point title	Number of Participants With at Least 2-Grade Shift From Baseline in Laboratory Parameters[12]

End point description:

Number of participants with at least 2-Grade shift from baseline in laboratory parameters are reported. Laboratory parameters included anaemia (AA), white blood cell decreased (WBCD), lymphocyte count decreased (LCD), lymphocyte count increased (LCI), neutrophil count decreased (NCD), platelet count decreased (PCD), hypoalbuminemia (HA),creatinine increased (CI), gamma glutamyl transferase increased (GGTI), hyponatremia (HN), hyperglycemia (HG), serum amylase increased (SAI), aspartate aminotransferase (AST) increased, blood bilirubin increased (BBI), lipase increased (LI), and hypertriglyceridemia (HTG). As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received. Here, number analyzed (n) denotes, number of participants analyzed for the specified laboratory parameter.

End point type	Primary

End point timeframe:

Day 1 (baseline) through 246.9 weeks (maximum observed duration)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: Participants				
AA (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	0	0	1	2
WBCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	0	0	0	0
LCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	0	1	1	4
LCI (n=0,0,0,0,0,0,0,0,0,17,18,39,41,44,37	0	0	0	0
NCD (n=3,3,3,17,18,40,38,38,20,17,18,37,37,36,31)	0	0	0	0
PCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,43,37)	0	0	0	0
HA (n=3,3,3,18,18,40,40,40,20,18,18,39,41,44,36)	1	0	0	6
CI (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	1	1	1	1
GGTI (n=3,3,3,18,18,0,0,0,0,0,0,0,0,0,0)	0	0	0	1
HN (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	1	0	1	2
HG (n=0,0,0,0,0,40,40,40,20,18,18,0,0,0,0	0	0	0	0

SAI (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	0
ASTI (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	0
BBI (n=0,0,0,0,0,0,0,0,0,18,18,39,40,43,37	0	0	0	0
LI (n=0,0,0,0,0,0,0,0,0,18,18,39,40,44,36	0	0	0	0
HTG (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	0

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: Participants				
AA (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	1	2	1	2
WBCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	0	1	1	2
LCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	4	5	7	8
LCI (n=0,0,0,0,0,0,0,0,0,17,18,39,41,44,37	0	0	0	0
NCD (n=3,3,3,17,18,40,38,38,20,17,18,37,37,36,31)	0	1	2	1
PCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,43,37)	1	0	1	0
HA (n=3,3,3,18,18,40,40,40,20,18,18,39,41,44,36)	3	6	6	6
CI (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	4	4	4	8
GGTI (n=3,3,3,18,18,0,0,0,0,0,0,0,0,0,0)	4	0	0	0
HN (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	3	3	5	5
HG (n=0,0,0,0,0,40,40,40,20,18,18,0,0,0,0	0	3	4	3
SAI (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	0
ASTI (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	0
BBI (n=0,0,0,0,0,0,0,0,0,18,18,39,40,43,37	0	0	0	0
LI (n=0,0,0,0,0,0,0,0,0,18,18,39,40,44,36	0	0	0	0
HTG (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	0

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	18	39
Units: Participants				
AA (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	0	1	2	2
WBCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	0	7	6	0
LCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	5	5	4	6
LCI (n=0,0,0,0,0,0,0,0,0,17,18,39,41,44,37	0	1	0	0
NCD (n=3,3,3,17,18,40,38,38,20,17,18,37,37,36,31)	0	9	11	0
PCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,43,37)	0	2	2	1
HA (n=3,3,3,18,18,40,40,40,20,18,18,39,41,44,36)	2	2	2	9
CI (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	2	4	2	0
GGTI (n=3,3,3,18,18,0,0,0,0,0,0,0,0,0,0)	0	0	0	0
HN (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	1	4	2	0
HG (n=0,0,0,0,0,40,40,40,20,18,18,0,0,0,0	5	1	5	0
SAI (n=0,0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	4	6	0
ASTI (n=0,0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	2	2	0
BBI (n=0,0,0,0,0,0,0,0,0,0,18,18,39,40,43,37	0	3	2	7
LI (n=0,0,0,0,0,0,0,0,0,0,18,18,39,40,44,36	0	5	10	5
HTG (n=0,0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	3	3	0

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	44	37	
Units: Participants				

AA (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	2	0	2	
WBCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	2	4	1	
LCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,44,37)	3	7	8	
LCI (n=0,0,0,0,0,0,0,0,0,17,18,39,41,44,37	0	0	2	
NCD (n=3,3,3,17,18,40,38,38,20,17,18,37,37,36,31)	1	1	1	
PCD (n=3,3,3,17,18,40,38,38,20,17,18,39,41,43,37)	0	0	3	
HA (n=3,3,3,18,18,40,40,40,20,18,18,39,41,44,36)	2	6	5	
CI (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	0	0	0	
GGTI (n=3,3,3,18,18,0,0,0,0,0,0,0,0,0,0)	0	0	0	
HN (n=3,3,3,18,18,40,40,40,20,18,18,0,0,	0	0	0	
HG (n=0,0,0,0,0,40,40,40,20,18,18,0,0,0,0	0	0	0	
SAI (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	
ASTI (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	
BBI (n=0,0,0,0,0,0,0,0,0,18,18,39,40,43,37	7	3	6	
LI (n=0,0,0,0,0,0,0,0,0,18,18,39,40,44,36	6	7	5	
HTG (n=0,0,0,0,0,0,0,0,0,18,18,0,0,0,0)	0	0	0	

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Participants With Dose Limiting Toxicities

End point description:

DLT:Any study drug related Grade (G) 3 or higher toxicity that occurred during DLT evaluation period including: any G>=3 noninfectious colitis/pneumonitis, liver transaminase elevation (TE) >=5 but =<8 upper limit of normal (ULN), any G4 immune-mediated AE (imAE)/immune-related AE (irAE), any G>=3 clinically significant non-hematologic toxicity, TE >8 ULN or total bilirubin (TBL) >5 ULN, increase in AST or ALT >=3 ULN along with TBL >=2 ULN, thrombocytopenia (G3/4 associated with G3/higher hemorrhage, G3 that did not improve by at least 1 grade within 7 days, and G4), G4 febrile neutropenia (FN), G3 FN of >=5 days and G3 FN regardless of duration, G4 neutropenia of >7 days, G3/4 neutropenia not associated with fever/systemic infection, and anemia (G3 and G4). DLT-Evaluable (DLTE) population included all participants enrolled in dose-escalation part who received at least 1 dose of study drugs and completed safety follow-up through DLTE period or experienced any DLT during DLTE period.

End point type	Primary

End point timeframe:

From Day 1 to 28 days after the first dose of study drugs

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.
[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	17
Units: Participants	0	0	0	0

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Objective Response (OR) in Exploration Cohorts C1A and C1B

End point title	Percentage of Participants With Objective Response (OR) in Exploration Cohorts C1A and C1B[15][16]

End point description:

The OR is defined as best overall response of confirmed complete response (CR) or confirmed partial response (PR) according to Response Evaluation Criteria in Solid Tumours Version 1.1 (RECIST V 1.1) guidelines. The CR is defined as disappearance of all target and non-target lesions and normalization of tumor marker level lesions. The PR is defined as at least a 30% decrease in the sum of the diameters of target lesions (compared to baseline) and no new nontarget lesion. A confirmed PR is defined as two PRs or an un-confirmed PR and an unconfirmed CR that were separated by at least 28 days with no evidence of progression in between. Intent-to-treat (ITT) population included participants who were randomized and were analyzed according to the treatment group they were randomized to.

End point type	Primary

End point timeframe:

Baseline (Days -28 to -1) through 54.8 months (maximum observed duration)

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.
[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	41		
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 10.3)	0 (0.0 to 9.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With OR

End point title	Percentage of Participants With OR[17]

End point description:

The OR is defined as best overall response of CR or confirmed PR according to RECIST V 1.1 guidelines. The CR is defined as disappearance of all target and non-target lesions and normalization of tumor marker level lesions. The PR is defined as at least a 30% decrease in the sum of the diameters of target lesions (compared to baseline) and no new nontarget lesion. A confirmed PR is defined as two PRs or an un-confirmed PR and an unconfirmed CR that were separated by at least 28 days with no evidence of progression in between. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

Baseline (Days -28 to -1) through 54.8 months (maximum observed duration)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 70.8)	0 (0.0 to 70.8)	0 (0.0 to 84.2)	0 (0.0 to 19.5)

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: Percentage of Participants				
number (confidence interval 95%)	0 (0.0 to 19.5)	7.5 (1.6 to 20.4)	5.0 (0.7 to 18.2)	0 (0.0 to 9.5)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	18	18	
Units: Percentage of Participants				
number (confidence interval 95%)	10.0 (1.2 to 31.7)	44.4 (23.0 to 72.2)	72.2 (46.5 to 90.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With OR in Exploration Cohorts C2A and C2B

End point title	Percentage of Participants With OR in Exploration Cohorts C2A and C2B[18]

End point description:

The OR is defined as best overall response of confirmed CR or confirmed PR according to RECIST V 1.1 guidelines. The CR is defined as disappearance of all target and non-target lesions and normalization of tumor marker level lesions. The PR is defined as at least a 30% decrease in the sum of the diameters of target lesions (compared to baseline) and no new nontarget lesion. A confirmed PR is defined as two PRs or an un-confirmed PR and an unconfirmed CR that were separated by at least 28 days with no evidence of progression in between. The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	37		
Units: Percentage of Participants				
number (confidence interval 95%)	11.4 (4.0 to 25.6)	5.4 (0.7 to 18.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Disease Control (DC)

End point title	Percentage of Participants with Disease Control (DC)[19]

End point description:

The DC is defined as best overall response of confirmed CR, confirmed PR, or stable disease (SD) based on RECIST v1.1. The CR is defined as disappearance of all target, non-target lesions and normalization of tumor marker level lesions. The PR is defined as at least a 30% decrease in the sum of the diameters of target lesions (compared to baseline) and no new nontarget lesion. A confirmed PR is defined as two PRs or an un-confirmed PR and an unconfirmed CR that were separated by at least 28 days with no evidence of progression in between. The SD is defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD. Participants with SD were included in the DC if they maintained SD for >= 8 weeks from start of treatment. The DCR16 and DCR24 are reported (participants with SD >= 16 weeks and >=24 weeks). As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: Percentage of Participants				
number (confidence interval 95%)				
DCR16	0 (0.0 to 70.8)	33.3 (0.8 to 90.6)	0 (0.0 to 70.8)	22.2 (6.4 to 47.6)
DCR24	0 (0.0 to 70.8)	0 (0.0 to 70.8)	0 (0.0 to 70.8)	0 (0.0 to 18.5)

End point values	Dose-escalation Cohort 5: Mona	Dose-expansion Cohort: Mona	Dose-expansion Cohort: Mona	Dose-expansion Cohort: Mona

	750 mg Q4W + Durva	750 mg Q2W + Durva (MSS-CRC)	750 mg Q2W + Durva (ovarian)	750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: Percentage of Participants				
number (confidence interval 95%)				
DCR16	27.8 (9.7 to 53.5)	30 (16.6 to 46.5)	30 (16.6 to 46.5)	25 (12.7 to 41.2)
DCR24	11.1 (1.4 to 34.7)	17.5 (7.3 to 32.8)	15 (5.7 to 29.8)	12.5 (4.2 to 26.8)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	18	18	
Units: Percentage of Participants				
number (confidence interval 95%)				
DCR16	40 (19.1 to 63.9)	77.8 (52.4 to 93.6)	88.9 (65.3 to 98.6)	
DCR24	25 (8.7 to 49.1)	66.7 (41.0 to 86.7)	77.8 (52.4 to 93.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with DC in Exploration Cohorts (C1A, C1B, C2A, and C2B)

End point title	Percentage of Participants with DC in Exploration Cohorts (C1A, C1B, C2A, and C2B)[20]

End point description:

The DC is defined as best overall response of confirmed CR, confirmed PR, or SD based on RECIST v1.1. The CR is defined as disappearance of all target and non-target lesions and normalization of tumor marker level lesions. The PR is defined as at least a 30% decrease in the sum of the diameters of target lesions (compared to baseline) and no new nontarget lesion. A confirmed PR is defined as two PRs or an un-confirmed PR and an unconfirmed CR that were separated by at least 28 days with no evidence of progression in between. The SD is defined as neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for disease progression. Participants with SD were included in the DC if they maintained SD for >= 8 weeks from start of treatment. The DCR16 and DCR24 are reported (participants with SD >= 16 weeks and >=24 weeks). The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	41	44	37
Units: Percentage of Participants				
number (confidence interval 95%)				
DCR16	17.5 (7.3 to 32.8)	34.1 (20.1 to 50.6)	59.1 (43.2 to 73.7)	56.8 (39.5 to 72.9)
DCR24	10.0 (2.8 to 23.7)	7.3 (1.5 to 19.9)	52.3 (36.7 to 67.5)	45.9 (29.5 to 63.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR)

End point title	Duration of Response (DoR)[21]

End point description:

The DoR is defined as the duration from the first documentation of OR (confirmed 2 CRs [disappearance of all target, non-target lesions and normalization of tumor marker level lesions] or confirmed 2 PRs [>= 30% decrease in the sum of diameters of target lesions compared to baseline and no new non-target lesion]) to the first documented PD based on RECIST v1.1 or death due to any cause, whichever occurred first. The 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. The DoR was evaluated using Kaplan-Meier method. The arbitrary number 99999 signified upper limit confidence interval (CI) could not be derived due to insufficient events being observed. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received. Participants who had achieved OR were evaluated for this outcome.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[22]	0[23]	0[24]	0[25]
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[22] - No participant has achieved OR in this treatment arm group.

[23] - No participant has achieved OR in this treatment arm group.

[24] - No participant has achieved OR in this treatment arm group.

[25] - No participant has achieved OR in this treatment arm group.

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[26]	3	2	0[27]
Units: Weeks				
median (confidence interval 95%)	(to)	16.1 (15.9 to 99999)	68.1 (24.0 to 99999)	(to)

Notes:

[26] - No participant has achieved OR in this treatment arm group.

[27] - No participant has achieved OR in this treatment arm group.

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	8	13	
Units: Weeks				
median (confidence interval 95%)	22.9 (10.1 to 99999)	66.1 (16.1 to 85.4)	72.3 (17.4 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: DoR in Exploration Cohorts (C1A, C1B, C2A, and C2B)

End point title	DoR in Exploration Cohorts (C1A, C1B, C2A, and C2B)[28]

End point description:

The DoR is defined as the duration from the first documentation of OR (confirmed 2 CRs [disappearance of all target, non-target lesions and normalization of tumor marker level lesions] or confirmed 2 PRs [(>= 30% decrease in the sum of diameters of target lesions compared to baseline and no new non-target lesion]) to the first documented PD based on RECIST v1.1 or death due to any cause, whichever occurred first. The 2 CRs and/or 2 PRs should be separated by at least 28 days with no evidence of progression in-between. The DoR was evaluated using Kaplan-Meier method. The arbitrary number 99999 signified upper limit CI could not be derived due to insufficient events being observed. The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to. Participants who had achieved OR were evaluated for this outcome

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[29]	0[30]	5	2
Units: Weeks				
median (confidence interval 95%)	(to)	(to)	32.1 (16.0 to 99999)	24.1 (12.1 to 99999)

Notes:

[29] - No participant has achieved OR in this treatment arm group.

[30] - No participant has achieved OR in this treatment arm group.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)[31]

End point description:

The PFS is defined as the time from the start of study treatment until the first documentation of PD based on RECIST v1.1 or death due to any cause, whichever occurred first. The PD is defined as at least a 20% increase in the sum of diameters of target lesions or unequivocal progression of existing non-target lesions, taking as reference the smallest sum on study and appearance of one or more new lesions. The arbitrary numbers 0.99999 and 99999 signified the data for lower and upper limit of CI could not be derived due to insufficient events being observed. The PFS was estimated using Kaplan-Meier method. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: Months				
median (confidence interval 95%)	1.8 (1.7 to 99999)	1.9 (1.8 to 99999)	1.9 (0.99999 to 99999)	2.0 (1.7 to 3.4)

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: Months				
median (confidence interval 95%)	1.8 (1.7 to 3.5)	1.9 (1.8 to 3.6)	1.8 (1.7 to 1.9)	1.8 (1.7 to 3.3)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	18	18	
Units: Months				
median (confidence interval 95%)	1.9 (1.7 to 3.7)	10.9 (5.7 to 17.7)	14.7 (5.8 to 20.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) in Exploration Cohorts (C1A, C1B, C2A, and C2B)

End point title	Progression-Free Survival (PFS) in Exploration Cohorts (C1A, C1B, C2A, and C2B)[32]

End point description:

The PFS is defined as the time from the start of study treatment until the first documentation of PD based on RECIST v1.1 or death due to any cause, whichever occurred first. The PD is defined as at least a 20% increase in the sum of diameters of target lesions or unequivocal progression of existing non-target lesions, taking as reference the smallest sum on study and appearance of one or more new lesions. The PFS was estimated using Kaplan-Meier method. The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	41	44	37
Units: Months				
median (confidence interval 95%)	1.8 (1.7 to 1.9)	2.0 (1.7 to 3.3)	5.3 (3.2 to 5.5)	4.4 (2.1 to 5.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival[33]

End point description:

The overall survival is defined as the time from the start of study treatment until death due to any cause. The OS was estimated using Kaplan-Meier method. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received. The arbitrary numbers 0.99999, 99999, and 99.999 signified the data for lower limit of CI, upper limit of CI, and median, respectively, could note be derived due to insufficient events being observed.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 months (maximum observed duration)

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: Months				
median (confidence interval 95%)	15.1 (0.99999 to 99999)	20.1 (18.6 to 99999)	99.999 (0.9999 to 99999)	8.1 (4.0 to 16.7)

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40

Units: Months				
median (confidence interval 95%)	13.4 (4.4 to 16.9)	10.6 (6.0 to 20.1)	16.7 (10.7 to 21.4)	11.0 (6.7 to 17.3)

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	18	18	
Units: Months				
median (confidence interval 95%)	8.8 (5.8 to 15.6)	25.6 (13.8 to 99999)	29.6 (19.8 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival in Exploration Cohorts (C1A, C1B, C2A, and C2B)

End point title	Overall Survival in Exploration Cohorts (C1A, C1B, C2A, and C2B)[34]

End point description:

The overall survival is defined as the time from the start of study treatment until death due to any cause. The overall survival was estimated using Kaplan-Meier method. The ITT population included participants who were randomized and were analyzed according to the treatment group they were randomized to.

End point type	Secondary

End point timeframe:

Baseline (-28 to -1 day) through 54.8 weeks (maximum observed duration)

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	41	44	37
Units: Months				
median (confidence interval 95%)	10.3 (4.3 to 12.7)	8.9 (6.8 to 11.3)	14.6 (10.0 to 19.4)	14.6 (7.2 to 18.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Serum Concentration (Cmax) of Monalizumab

End point title	Maximum Observed Serum Concentration (Cmax) of Monalizumab[35]

End point description:

Serum Cmax of monalizumab are reported. The arbitrary number 99999 signified standard deviation was not reported as only one participant was evaluable for the specified arm. Pharmacokinetic evaluable population included participants who received at least 1 dose of durvalumab and/or monalizumab and had at least 1 post-treatment sample available. Number of subjects analyzed denotes those participants who had adequate PK sample available for analysis.

End point type	Secondary

End point timeframe:

Pre-dose and end of infusion (EOI) on Day 85 after durvalumab infusion for all cohorts, additionally, EOI after end of cetuximab infusion (Cohort C1A) and pre-dose and EOI after end of monalizumab and cetuximab infusion (Cohort C1B)

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	1	6
Units: µg/mL				
arithmetic mean (standard deviation)	7.85 (± 99999)	43.62 (± 12.54)	144.88 (± 99999)	245.18 (± 142.35)

End point values	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	9	10	11
Units: µg/mL				
arithmetic mean (standard deviation)	304.48 (± 66.75)	281.53 (± 155.57)	346.85 (± 91.06)	388.60 (± 194.64)

End point values	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	Dose-escalation Cohort4+Dose-expansion: Mona 750mg Q2W + Durva	

Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	19	19	60	
Units: µg/mL				
arithmetic mean (standard deviation)	289.25 (± 194.59)	409.93 (± 175.43)	315.74 (± 129.08)	

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Observed Serum Concentration (Cmin) of Monalizumab

End point title	Minimum Observed Serum Concentration (Cmin) of Monalizumab[36]

End point description:

Serum Cmin of monalizumab are reported. The arbitrary number 99999 signified standard deviation was not reported as only one participant was evaluable for the specified arm. Pharmacokinetic evaluable population included participants who received at least 1 dose of durvalumab and/or monalizumab and had at least 1 post-treatment sample available. Number of subjects analyzed denotes those participants who had adequate PK sample available for analysis.

End point type	Secondary

End point timeframe:

Pre-dose and end of infusion (EOI) on Day 85 after durvalumab infusion for all cohorts, additionally, EOI after end of cetuximab infusion (Cohort C1A) and pre-dose and EOI after end of monalizumab and cetuximab infusion (Cohort C1B)

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	1	6
Units: µg/mL				
arithmetic mean (standard deviation)	7.45 (± 99999)	18.16 (± 6.70)	92.55 (± 99999)	67.75 (± 57.82)

End point values	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	11
Units: µg/mL				
arithmetic mean (standard deviation)	141.39 (± 57.01)	109.18 (± 45.54)	129.59 (± 45.72)	172.90 (± 84.55)

End point values	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	Dose-escalation Cohort4+Dose-expansion: Mona 750mg Q2W + Durva	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	22	22	61	
Units: µg/mL				
arithmetic mean (standard deviation)	148.05 (± 70.23)	185.60 (± 105.68)	145.04 (± 76.34)	

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Durvalumab

End point title	Serum Concentration of Durvalumab

End point description:

Serum concentration of durvalumab is reported. Pharmacokinetic evaluable population included participants who received at least 1 dose of durvalumab and/or monalizumab and had at least 1 post-treatment sample available. Number analyzed (n) denotes those participants who had adequate PK sample available for analysis for specified time point.

End point type	Secondary

End point timeframe:

Pre-dose (PRE) on Day 1 of Weeks 1, 5, 9, 13, and 25 and post-dose (POST) on Day 1 of Weeks 1 and 13

End point values	Dose-escalation (1-5) + dose-expansion + dose-exploration			
Subject group type	Subject analysis set			
Number of subjects analysed	315			
Units: µg/mL				
arithmetic mean (standard deviation)				
Week 1 Day 1 (PRE) (n=287)	0.100 (± 0.63)			
Week 1 Day 1 (POST) (n=285)	399 (± 157)			
Week 5 Day 1 (PRE) (n=248)	90.8 (± 95.0)			
Week 9 Day 1 (PRE) (n=193)	127 (± 148)			
Week 13 Day 1 (PRE) (n=140)	142 (± 123)			
Week 13 Day 1 (POST) (n=126)	497 (± 277)			
Week 25 Day 1 (PRE) (n=79)	149 (± 109)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Cetuximab

End point title	Serum Concentration of Cetuximab

End point description:

Serum concentration of cetuximab is reported. Pharmacokinetic evaluable population included participants who received at least 1 dose of durvalumab and/or monalizumab and had at least 1 post-treatment sample available. Number analyzed (n) denotes those participants who had adequate PK sample available for analysis for specified time point

End point type	Secondary

End point timeframe:

Pre-dose (PRE) on Day 1 of Week 1, 5, 9, 13, and post-dose (POST) on Day 1 of Week 1, 5, and 13 at the end of infusion

End point values	Exploration Cohorts A2, C1A, C2A, C1B, and C2B			
Subject group type	Subject analysis set			
Number of subjects analysed	77			
Units: µg/mL				
arithmetic mean (standard deviation)				
Week 1 Day 1 (PRE) (n=54)	0.025 (± 0.00)			
Week 1 Day 1 (POST) (n=70)	400 (± 138)			
Week 5 Day 1 (PRE) (n=48)	73.6 (± 108.0)			
Week 5 Day 1 (POST) (n=6)	344 (± 161)			
Week 9 Day 1 (PRE) (n=18)	97.7 (± 137)			
Week 13 Day 1 (PRE) (n=19)	61.7 (± 113)			
Week 13 Day 1 (POST) (n=20)	387 (± 101)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive Anti-Drug Antibodies (ADA) to Monalizumab

End point title	Number of Participants With Positive Anti-Drug Antibodies (ADA) to Monalizumab

End point description:

Number of participants with positive ADA to monalizumab are reported. Persistent positive is defined as positive at >=2 post-baseline assessments (with >=16 weeks between first and last positive) or positive

at last post-baseline assessment. Transient positive is defined as negative at last post-baseline assessment and positive at only one post-baseline assessment or at >=2 post-baseline assessments (with <16 weeks between first and last positive). Treatment-boosted ADA is defined as baseline ADA titer that was boosted to a 4-fold or higher-level following drug administration. Treatment-emergent ADA is defined as the sum of treatment-induced ADA (post-baseline positive only) and treatment-boosted ADA. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received. Here, number of subjects analyzed denotes those participants who had adequate ADA sample.

End point type	Secondary

End point timeframe:

Day 1 through 54.8 months (Day 1 of Weeks 1, 5, 13, and 25, and 90 days after the last dose of monalizumab)

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	15
Units: Participants				
Persistent Positive	0	0	0	2
Transient Positive	0	0	0	1
Treatment-boosted ADA	0	0	0	0
Treatment-emergent ADA	0	0	0	3

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	36	35	32
Units: Participants				
Persistent Positive	0	10	5	4
Transient Positive	0	1	2	1
Treatment-boosted ADA	0	0	0	0
Treatment-emergent ADA	0	11	7	5

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	16	18	30
Units: Participants				

Persistent Positive	2	0	1	5
Transient Positive	2	0	0	1
Treatment-boosted ADA	0	0	0	0
Treatment-emergent ADA	4	0	1	6

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	37	34	
Units: Participants				
Persistent Positive	5	3	5	
Transient Positive	1	2	0	
Treatment-boosted ADA	0	0	0	
Treatment-emergent ADA	6	5	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive ADA to Durvalumab

End point title	Number of Participants With Positive ADA to Durvalumab

End point description:

Number of participants with positive ADA to monalizumab are reported. The persistent positive is defined as positive at >=2 post-baseline assessments (with >=16 weeks between first and last positive) or positive at last post-baseline assessment. The transient positive is defined as negative at last post-baseline assessment and positive at only one post-baseline assessment or at >= 2 post-baseline assessments (with <16 weeks between first and last positive). The treatment-boosted ADA is defined as baseline ADA titer that was boosted to a 4-fold or higher-level following drug administration. The treatment-emergent ADA is defined as the sum of treatment-induced ADA (post-baseline positive only) and treatment-boosted ADA. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received. Here, number of subjects analyzed denotes those participants who had adequate ADA sample.

End point type	Secondary

End point timeframe:

Day 1 through 54.8 months (Day 1 of Weeks 1, 5, 13, and 25, and 90 days after the last dose of monalizumab)

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	15
Units: Participants				
Persistent Positive	0	0	0	0

Transient Positive	0	0	0	0
Treatment-boosted ADA	0	0	0	0
Treatment-emergent ADA	0	0	0	0

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	36	33	31
Units: Participants				
Persistent Positive	0	1	0	0
Transient Positive	1	0	0	0
Treatment-boosted ADA	0	0	0	0
Treatment-emergent ADA	1	1	0	0

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	17	18	30
Units: Participants				
Persistent Positive	0	0	0	0
Transient Positive	0	0	0	0
Treatment-boosted ADA	0	0	0	0
Treatment-emergent ADA	0	0	0	0

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	2	39	1	
Units: Participants				
Persistent Positive	0	0	0	
Transient Positive	0	0	0	
Treatment-boosted ADA	0	0	0	
Treatment-emergent ADA	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Positive ADA to Cetuximab

End point title	Number of Participants With Positive ADA to Cetuximab[37]

End point description:

Number of participants with positive ADA to cetuximab are reported. The persistent positive is defined as positive at >=2 post-baseline assessments (with >=16 weeks between first and last positive) or positive at last post-baseline assessment. The transient positive is defined as negative at last post-baseline assessment and positive at only one post-baseline assessment or at >= 2 post-baseline assessments (with <16 weeks between first and last positive). The treatment-boosted ADA is defined as baseline ADA titer that was boosted to a 4-fold or higher-level following drug administration. The treatment-emergent ADA is defined as the sum of treatment-induced ADA (post-baseline positive only) and treatment-boosted ADA. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received. Here, number of subjects analyzed denotes those participants who had adequate ADA sample.

End point type	Secondary

End point timeframe:

Day 1 through 54.8 months (Day 1 of Weeks 1, 5, 9 [if EOT occurred], and 13, and 30 days after the last dose of monalizumab)

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only those baseline period arms for which analysis was planned were reported in the end point.

End point values	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	28	35	1
Units: Participants				
Persistent Positive	0	1	0	0
Transient Positive	0	0	0	0
Treatment-boosted ADA	0	0	0	0
Treatment-emergent ADA	0	1	0	0

End point values	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu			
Subject group type	Reporting group			
Number of subjects analysed	0[38]			
Units: Participants				

Persistent Positive				
Transient Positive				
Treatment-boosted ADA				
Treatment-emergent ADA				

Notes:

[38] - No participant had adequate ADA sample.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Programmed Death Ligand 1 (PD-L1) Expression in Pretreatment Tumor Biopsies

End point title	Number of Participants With Programmed Death Ligand 1 (PD-L1) Expression in Pretreatment Tumor Biopsies

End point description:

Number of participants with PD-L1 expression in pre-treatment tumor biopsies is reported. The PD-L1 expression on more than 25% tumor cells (TC) was considered as high, while TC<25% was considered to be low/negative. The TC>=1% was considered as TC positive, while TC<1% was considered to be TC negative. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received. Here, number of subjects analyzed denotes those participants for whom PD-L1 testing was performed, and for whom PD-L1 status was obtained.

End point type	Secondary

End point timeframe:

Screening (Days -28 to -1)

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	13
Units: Participants				
TC>=25%	0	0	0	2
TC<25%	3	3	3	11
TC>=1%	1	1	1	6
TC<1%	2	2	2	7

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	29	37	32
Units: Participants				
TC>=25%	1	0	5	1

TC<25%	13	29	32	31
TC>=1%	2	5	22	16
TC<1%	12	24	15	16

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	16	18	31
Units: Participants				
TC>=25%	6	0	0	0
TC<25%	10	16	18	31
TC>=1%	8	3	0	5
TC<1%	8	13	18	26

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	36	32	
Units: Participants				
TC>=25%	1	1	0	
TC<25%	32	35	32	
TC>=1%	7	7	5	
TC<1%	26	29	27	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Human Leukocyte Antigen (HLA)-E Expression in Pretreatment Tumor Biopsies

End point title	Number of Participants With Human Leukocyte Antigen (HLA)-E Expression in Pretreatment Tumor Biopsies

End point description:

The HLA-E expression in pre-treatment tumor biopsies is reported. As-treated population included participants who received any study drugs and were analyzed according to the treatment they actually received.

End point type	Secondary

End point timeframe:

Screening (Days -28 to -1)

End point values	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	18
Units: Participants				
HLA-E Carcinoma	3	3	3	12
HLA-E Lymphocyte	3	3	3	12
HLA-E Endothelium	3	3	3	13

End point values	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	40	40	40
Units: Participants				
HLA-E Carcinoma	13	28	36	32
HLA-E Lymphocyte	13	30	37	32
HLA-E Endothelium	13	30	37	33

End point values	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration Cohort A1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva	Exploration CohortA2: Mona 750 mg Q2W+Durva+ mFOLFOX6+Cetu	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	18	18	39
Units: Participants				
HLA-E Carcinoma	16	16	17	30
HLA-E Lymphocyte	17	16	17	29
HLA-E Endothelium	17	16	17	30

End point values	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	41	44	37	
Units: Participants				
HLA-E Carcinoma	33	34	32	
HLA-E Lymphocyte	32	34	32	
HLA-E Endothelium	31	34	32	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Day 1 through 246.9 weeks (maximum observed duration)

Adverse event reporting additional description:

Total number of death data was analysed as per ITT population, and AE/SAE data was analysed as per As-treated population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 225 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 75 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva

Reporting group description:

Participants received intravenous (IV) infusions of durvalumab 1500 mg every 4 weeks (Q4W) in combination with monalizumab 22.5 mg every 2 weeks (Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed disease progression (PD), or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)

Reporting group description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q4W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva

Reporting group description:

Participants received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu

Reporting group description:

Participants with recurrent or metastatic third-line (3L) RAS mutant MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)

Reporting group description:

Participants with non-small cell lung cancer (NSCLC) received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation

of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration CohortA1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva

Reporting group description:

Participants with first-line (1L) MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus mFOLFOX (oxaliplatin 85 mg/m^2 IV infusion, folinic acid 400 mg/m^2 infusion, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of bevacizumab 5 mg/kg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu

Reporting group description:

Participants with 1L MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W, plus mFOLFOX6 (oxaliplatin 85 mg/m^2, folinic acid 400 mg/m^2, fluorouracil 400 mg/m^2 IV bolus, followed by 2400 mg/m^2 continuous IV infusion over 46 to 48 hours on Day 1) Q2W plus IV infusion of cetuximab (loading dose of 400 mg/m^2 on Day 1, followed by maintenance dose of 250 mg/m^2 IV infusion every week starting on Day 8, then changed to 500 mg/m^2 IV infusion Q2W) up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)

Reporting group description:

Participants with endometrial MSS received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)

Reporting group description:

Participants with ovarian cancer received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS mutant MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusions of durvalumab 1500 mg Q4W in combination with monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Reporting group title	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu

Reporting group description:

Participants with recurrent or metastatic 3L RAS/BRAF wild type MSS-CRC received IV infusion of monalizumab 750 mg Q2W plus IV infusion of cetuximab 500 mg/m^2 on Day 1 then 500 mg/m^2 IV infusion Q2W starting on Day 15 up to 3 years until unacceptable toxicity, documentation of confirmed PD, or documentation of subject withdrawal for another reason.

Serious adverse events	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
number of deaths (all causes)	0	3	1

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed[1]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed[2]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed[3]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[4]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed[5]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			
subjects affected / exposed[6]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed[7]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Fatigue			

subjects affected / exposed[8]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed[9]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed[10]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed[11]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[12]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[13]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[14]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[15]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			

subjects affected / exposed[16]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 shock			
subjects affected / exposed[17]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Intermenstrual bleeding			
subjects affected / exposed[18]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 failure			
subjects affected / exposed[19]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[20]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed[21]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[22]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[23]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[24]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[25]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[26]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[27]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed[28]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Platelet count decreased			
subjects affected / exposed[29]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed[30]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Infusion related reaction			
subjects affected / exposed[31]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 limb fracture			
subjects affected / exposed[32]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed[33]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[34]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[35]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed[36]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[37]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed[38]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myocarditis			
subjects affected / exposed[39]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed[40]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Encephalitis autoimmune			
subjects affected / exposed[41]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed[42]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed[43]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed[44]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[45]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed[46]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[47]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[48]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[49]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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[50]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[51]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[52]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Colitis			
subjects affected / exposed[53]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			
subjects affected / exposed[54]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[55]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[56]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed[57]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 fistula			
subjects affected / exposed[58]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[59]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[60]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed[61]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[62]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[63]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 stenosis			
subjects affected / exposed[64]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 intestine perforation			
subjects affected / exposed[65]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[66]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[67]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[68]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed[69]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[70]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed[71]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed[72]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[73]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[74]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[75]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[76]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[77]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed[78]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			

subjects affected / exposed[79]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[80]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[81]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed[82]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[83]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 sepsis			
subjects affected / exposed[84]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[85]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed[86]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Encephalomyelitis			
subjects affected / exposed[87]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed[88]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed[89]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed[90]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed[91]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed[92]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed[93]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[94]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed[95]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[96]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[97]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[98]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed[99]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed[100]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[101]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[102]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed[103]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[104]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed[105]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed[106]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed[107]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed[108]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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[109]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed[110]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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	Dose-expansion Cohort: Mona 750 mg Q2W + Durva	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva

	(MSS-CRC)		
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 40 (27.50%)	4 / 18 (22.22%)	8 / 18 (44.44%)
number of deaths (all causes)	29	14	16
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed[1]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed[2]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed[3]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed[4]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed[5]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			
subjects affected / exposed[6]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			

subjects affected / exposed[7]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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			
Fatigue			
subjects affected / exposed[8]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed[9]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed[10]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed[11]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[12]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[13]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[14]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (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[15]	0 / 40 (0.00%)	1 / 18 (5.56%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed[16]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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 shock			
subjects affected / exposed[17]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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			
Intermenstrual bleeding			
subjects affected / exposed[18]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed[19]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[20]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (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
Haemoptysis			
subjects affected / exposed[21]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[22]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[23]	1 / 40 (2.50%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed[24]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[25]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[26]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[27]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed[28]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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			
Platelet count decreased			
subjects affected / exposed[29]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			

subjects affected / exposed[30]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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			
Infusion related reaction			
subjects affected / exposed[31]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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 limb fracture			
subjects affected / exposed[32]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed[33]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[34]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[35]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed[36]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[37]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myocardial ischaemia			
subjects affected / exposed[38]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed[39]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed[40]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Encephalitis autoimmune			
subjects affected / exposed[41]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed[42]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed[43]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed[44]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[45]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			

subjects affected / exposed[46]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[47]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
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[48]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[49]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (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[50]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[51]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[52]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (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
Colitis			
subjects affected / exposed[53]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			

subjects affected / exposed[54]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[55]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed[56]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed[57]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal fistula			
subjects affected / exposed[58]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[59]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed[60]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[61]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[62]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
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[63]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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 stenosis			
subjects affected / exposed[64]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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 intestine perforation			
subjects affected / exposed[65]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[66]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[67]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[68]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed[69]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
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[70]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (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[71]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed[72]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[73]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (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
Cholangitis			
subjects affected / exposed[74]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[75]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[76]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
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[77]	1 / 40 (2.50%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			

subjects affected / exposed[78]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			
subjects affected / exposed[79]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed[80]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[81]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed[82]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[83]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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 sepsis			
subjects affected / exposed[84]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[85]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Device related infection			
subjects affected / exposed[86]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalomyelitis			
subjects affected / exposed[87]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed[88]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed[89]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed[90]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed[91]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed[92]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
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			
subjects affected / exposed[93]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[94]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyelonephritis			
subjects affected / exposed[95]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed[96]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[97]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed[98]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed[99]	0 / 40 (0.00%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed[100]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[101]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[102]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed[103]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
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[104]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed[105]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed[106]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed[107]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed[108]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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[109]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			

subjects affected / exposed[110]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
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	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration CohortA1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 40 (25.00%)	7 / 20 (35.00%)	10 / 18 (55.56%)
number of deaths (all causes)	29	19	10
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed[1]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed[2]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed[3]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed[4]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed[5]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			

subjects affected / exposed[6]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed[7]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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			
Fatigue			
subjects affected / exposed[8]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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
Hypothermia			
subjects affected / exposed[9]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed[10]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed[11]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[12]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[13]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
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[14]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[15]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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
Systemic inflammatory response syndrome			
subjects affected / exposed[16]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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 shock			
subjects affected / exposed[17]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
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			
Intermenstrual bleeding			
subjects affected / exposed[18]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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 failure			
subjects affected / exposed[19]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[20]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed[21]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed[22]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[23]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[24]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed[25]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
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[26]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[27]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed[28]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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			

Platelet count decreased			
subjects affected / exposed[29]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed[30]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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			
Infusion related reaction			
subjects affected / exposed[31]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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 limb fracture			
subjects affected / exposed[32]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed[33]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[34]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[35]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed[36]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[37]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed[38]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed[39]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed[40]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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			
Encephalitis autoimmune			
subjects affected / exposed[41]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed[42]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed[43]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed[44]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[45]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed[46]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[47]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[48]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed[49]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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[50]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[51]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[52]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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
Colitis			

subjects affected / exposed[53]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			
subjects affected / exposed[54]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed[55]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[56]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed[57]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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 fistula			
subjects affected / exposed[58]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[59]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[60]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[61]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[62]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[63]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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 stenosis			
subjects affected / exposed[64]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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 intestine perforation			
subjects affected / exposed[65]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[66]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed[67]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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
Pancreatitis			
subjects affected / exposed[68]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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
Small intestinal haemorrhage			

subjects affected / exposed[69]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[70]	2 / 39 (5.13%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed[71]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed[72]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[73]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[74]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[75]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
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[76]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[77]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed[78]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			
subjects affected / exposed[79]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[80]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[81]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed[82]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[83]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (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
Biliary sepsis			
subjects affected / exposed[84]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[85]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed[86]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalomyelitis			
subjects affected / exposed[87]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed[88]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed[89]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed[90]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed[91]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metapneumovirus infection			
subjects affected / exposed[92]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			

subjects affected / exposed[93]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed[94]	1 / 39 (2.56%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed[95]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[96]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (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
Sepsis			
subjects affected / exposed[97]	0 / 39 (0.00%)	1 / 20 (5.00%)	1 / 18 (5.56%)
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[98]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
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 infection			
subjects affected / exposed[99]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed[100]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed[101]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[102]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed[103]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[104]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed[105]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed[106]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed[107]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed[108]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
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[109]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed[110]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
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	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 18 (61.11%)	17 / 40 (42.50%)	16 / 40 (40.00%)
number of deaths (all causes)	8	28	34
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed[1]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed[2]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed[3]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[4]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			

subjects affected / exposed[5]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			
subjects affected / exposed[6]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed[7]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed[8]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed[9]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed[10]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed[11]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[12]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[13]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[14]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[15]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed[16]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed[17]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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			
Intermenstrual bleeding			
subjects affected / exposed[18]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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 failure			
subjects affected / exposed[19]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[20]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed[21]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[22]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[23]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (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
Pneumonitis			
subjects affected / exposed[24]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[25]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (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 embolism			
subjects affected / exposed[26]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed[27]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (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
Psychiatric disorders			
Bipolar disorder			

subjects affected / exposed[28]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed[29]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed[30]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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			
Infusion related reaction			
subjects affected / exposed[31]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed[32]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed[33]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed[34]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[35]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
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 fibrillation			
subjects affected / exposed[36]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed[37]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed[38]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed[39]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed[40]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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			
Encephalitis autoimmune			
subjects affected / exposed[41]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed[42]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed[43]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			

subjects affected / exposed[44]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[45]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (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
Transient ischaemic attack			
subjects affected / exposed[46]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[47]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[48]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed[49]	0 / 18 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed[50]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[51]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[52]	0 / 18 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed[53]	0 / 18 (0.00%)	0 / 40 (0.00%)	2 / 40 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			
subjects affected / exposed[54]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[55]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[56]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed[57]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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 fistula			
subjects affected / exposed[58]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed[59]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[60]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[61]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (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
Intestinal obstruction			
subjects affected / exposed[62]	1 / 18 (5.56%)	1 / 40 (2.50%)	3 / 40 (7.50%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed[63]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (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 stenosis			
subjects affected / exposed[64]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (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 intestine perforation			
subjects affected / exposed[65]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed[66]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[67]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[68]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed[69]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[70]	0 / 18 (0.00%)	1 / 40 (2.50%)	3 / 40 (7.50%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed[71]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed[72]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[73]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[74]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[75]	1 / 18 (5.56%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed[76]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[77]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed[78]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			
subjects affected / exposed[79]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[80]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[81]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed[82]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed[83]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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 sepsis			
subjects affected / exposed[84]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[85]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed[86]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalomyelitis			
subjects affected / exposed[87]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed[88]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed[89]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed[90]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed[91]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			

subjects affected / exposed[92]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed[93]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[94]	0 / 18 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed[95]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[96]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed[97]	3 / 18 (16.67%)	0 / 40 (0.00%)	0 / 40 (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
Upper respiratory tract infection			
subjects affected / exposed[98]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed[99]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed[100]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[101]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[102]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed[103]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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[104]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed[105]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed[106]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (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
Hypocalcaemia			
subjects affected / exposed[107]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			

subjects affected / exposed[108]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (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
Hyponatraemia			
subjects affected / exposed[109]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed[110]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
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	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 41 (12.20%)	9 / 44 (20.45%)	11 / 37 (29.73%)
number of deaths (all causes)	29	29	27
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed[1]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed[2]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Embolism			
subjects affected / exposed[3]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[4]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (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
Lymphoedema			
subjects affected / exposed[5]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			
subjects affected / exposed[6]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (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
Vena cava thrombosis			
subjects affected / exposed[7]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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			
Fatigue			
subjects affected / exposed[8]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed[9]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed[10]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed[11]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Non-cardiac chest pain			

subjects affected / exposed[12]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed[13]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[14]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[15]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed[16]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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 shock			
subjects affected / exposed[17]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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			
Intermenstrual bleeding			
subjects affected / exposed[18]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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 failure			

subjects affected / exposed[19]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
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[20]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed[21]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[22]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
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[23]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[24]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[25]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[26]	1 / 41 (2.44%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed[27]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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			
Bipolar disorder			
subjects affected / exposed[28]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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			
Platelet count decreased			
subjects affected / exposed[29]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed[30]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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			
Infusion related reaction			
subjects affected / exposed[31]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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 limb fracture			
subjects affected / exposed[32]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed[33]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[34]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[35]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed[36]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[37]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed[38]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed[39]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed[40]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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			
Encephalitis autoimmune			
subjects affected / exposed[41]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed[42]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolic encephalopathy			
subjects affected / exposed[43]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed[44]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (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
Seizure			
subjects affected / exposed[45]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed[46]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[47]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[48]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[49]	0 / 41 (0.00%)	1 / 44 (2.27%)	3 / 37 (8.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed[50]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain upper			
subjects affected / exposed[51]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (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
Ascites			
subjects affected / exposed[52]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[53]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic fistula			
subjects affected / exposed[54]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[55]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed[56]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed[57]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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 fistula			
subjects affected / exposed[58]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[59]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[60]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[61]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[62]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
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[63]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
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 stenosis			
subjects affected / exposed[64]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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 intestine perforation			
subjects affected / exposed[65]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[66]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[67]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[68]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed[69]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[70]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (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
Vomiting			
subjects affected / exposed[71]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed[72]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary obstruction			
subjects affected / exposed[73]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[74]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed[75]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed[76]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[77]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritis			
subjects affected / exposed[78]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcapsular renal haematoma			
subjects affected / exposed[79]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[80]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[81]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed[82]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[83]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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 sepsis			
subjects affected / exposed[84]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
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[85]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (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
Device related infection			
subjects affected / exposed[86]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalomyelitis			
subjects affected / exposed[87]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed[88]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of chronic obstructive airways disease			
subjects affected / exposed[89]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kidney infection			
subjects affected / exposed[90]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lower respiratory tract infection			
subjects affected / exposed[91]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed[92]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed[93]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[94]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed[95]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[96]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[97]	0 / 41 (0.00%)	1 / 44 (2.27%)	2 / 37 (5.41%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Upper respiratory tract infection			
subjects affected / exposed[98]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
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 infection			

subjects affected / exposed[99]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (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
Urosepsis			
subjects affected / exposed[100]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[101]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed[102]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed[103]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[104]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed[105]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed[106]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			

subjects affected / exposed[107]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed[108]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
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[109]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed[110]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each

adverse event is less than the "Total number of subjects exposed".

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[13] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[14] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[15] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[16] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[17] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[19] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[20] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

[21] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[22] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[23] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[25] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[26] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[27] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[28] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[29] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".
[30] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
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Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Dose-escalation Cohort 3: Mona 225 mg Q2W + Durva	Dose-escalation Cohort 2: Mona 75 mg Q2W + Durva	Dose-escalation Cohort 1: Mona 22.5 mg Q2W + Durva
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed[111]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed[112]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malignant ascites			

subjects affected / exposed[113]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed[114]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed[115]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed[116]	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed[117]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed[118]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed[119]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed[120]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed[121]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed[122]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed[123]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed[124]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lymphoedema			
subjects affected / exposed[125]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed[126]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed[127]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed[128]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed[129]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed[130]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed[131]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site dermatitis			
subjects affected / exposed[132]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site erosion			
subjects affected / exposed[133]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed[134]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed[135]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed[136]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed[137]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Complication associated with device			
subjects affected / exposed[138]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed[139]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed[140]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed[141]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed[142]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed[143]	2 / 3 (66.67%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	2	1	3
Gait disturbance			
subjects affected / exposed[144]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed[145]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed[146]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed[147]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hernia pain			

subjects affected / exposed[148]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed[149]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Injection site discomfort			
subjects affected / exposed[150]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed[151]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed[152]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed[153]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical device pain			
subjects affected / exposed[154]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed[155]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed[156]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed[157]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed[158]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed[159]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed[160]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed[161]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Secretion discharge			
subjects affected / exposed[162]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed[163]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed[164]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed[165]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed[166]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed[167]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related hypersensitivity reaction			
subjects affected / exposed[168]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed[169]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed[170]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Erectile dysfunction			

subjects affected / exposed[171]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Female genital tract fistula			
subjects affected / exposed[172]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed[173]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed[174]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed[175]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ovarian mass			
subjects affected / exposed[176]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed[177]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed[178]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scrotal dermatitis			
subjects affected / exposed[179]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed[180]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed[181]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed[182]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			

subjects affected / exposed[183]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed[184]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed[185]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed[186]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed[187]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dry throat			
subjects affected / exposed[188]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed[189]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed[190]	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Dyspnoea exertional			
subjects affected / exposed[191]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed[192]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed[193]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiccups			

subjects affected / exposed[194]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed[195]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed[196]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed[197]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal dryness			
subjects affected / exposed[198]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed[199]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
subjects affected / exposed[200]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed[201]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed[202]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed[203]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed[204]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed[205]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			

subjects affected / exposed[206]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed[207]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary pain			
subjects affected / exposed[208]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed[209]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed[210]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed[211]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus pain			
subjects affected / exposed[212]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed[213]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed[214]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed[215]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed[216]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed[217]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			

subjects affected / exposed[218]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed[219]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed[220]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed[221]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed[222]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed[223]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucinations, mixed			
subjects affected / exposed[224]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed[225]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed[226]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed[227]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed[228]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mood swings			
subjects affected / exposed[229]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nervousness			
subjects affected / exposed[230]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed[231]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion			
subjects affected / exposed[232]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed[233]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed[234]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Amylase			
subjects affected / exposed[235]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed[236]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed[237]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Bacterial test positive			
subjects affected / exposed[238]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed[239]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed[240]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed[241]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed[242]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed[243]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed[244]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood fibrinogen increased			
subjects affected / exposed[245]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed[246]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed[247]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed[248]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed[249]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed[250]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed[251]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood uric acid decreased			

subjects affected / exposed[252]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed[253]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Carbohydrate antigen 125 increased			
subjects affected / exposed[254]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed[255]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed[256]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed[257]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General physical condition abnormal			
subjects affected / exposed[258]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed[259]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed[260]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed[261]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed[262]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			

subjects affected / exposed[263]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed[264]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed[265]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed[266]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed[267]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed[268]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed[269]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed[270]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed[271]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed[272]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed[273]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed[274]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed[275]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed[276]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed[277]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed[278]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed[279]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail injury			
subjects affected / exposed[280]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed[281]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed[282]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed[283]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed[284]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed[285]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stoma site discomfort			

subjects affected / exposed[286]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed[287]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed[288]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed[289]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed[290]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[291]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed[292]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed[293]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree			
subjects affected / exposed[294]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed[295]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed[296]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conduction disorder			
subjects affected / exposed[297]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Myocarditis			
subjects affected / exposed[298]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed[299]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed[300]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed[301]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed[302]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular tachycardia			
subjects affected / exposed[303]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed[304]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed[305]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed[306]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed[307]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Central nervous system necrosis			
subjects affected / exposed[308]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cerebrospinal fluid leakage			

subjects affected / exposed[309]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed[310]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed[311]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed[312]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed[313]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed[314]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed[315]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Encephalomalacia			
subjects affected / exposed[316]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed[317]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed[318]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypersomnia			
subjects affected / exposed[319]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed[320]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			

subjects affected / exposed[321]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lhermitte's sign			
subjects affected / exposed[322]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed[323]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed[324]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic encephalopathy			
subjects affected / exposed[325]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed[326]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed[327]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed[328]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed[329]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed[330]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed[331]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed[332]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed[333]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed[334]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed[335]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed[336]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed[337]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[338]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed[339]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed[340]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed[341]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed[342]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed[343]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed[344]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[345]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed[346]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed[347]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed[348]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed[349]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed[350]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed[351]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed[352]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed[353]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed[354]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed[355]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			

subjects affected / exposed[356]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed[357]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed[358]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed[359]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed[360]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed[361]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed[362]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed[363]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed[364]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed[365]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed[366]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed[367]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pterygium			

subjects affected / exposed[368]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed[369]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed[370]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed[371]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed[372]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed[373]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Abdominal hernia			
subjects affected / exposed[374]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed[375]	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	3	0	2
Abdominal pain lower			
subjects affected / exposed[376]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed[377]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal rigidity			
subjects affected / exposed[378]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed[379]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Anal incontinence			
subjects affected / exposed[380]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed[381]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed[382]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Autoimmune pancreatitis			
subjects affected / exposed[383]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed[384]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed[385]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Defaecation urgency			
subjects affected / exposed[386]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed[387]	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 3 (100.00%)
occurrences (all)	1	2	3
Dry mouth			
subjects affected / exposed[388]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed[389]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed[390]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epigastric discomfort			
subjects affected / exposed[391]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Eructation			
subjects affected / exposed[392]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed[393]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed[394]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed[395]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed[396]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed[397]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed[398]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed[399]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed[400]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed[401]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed[402]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia teeth			
subjects affected / exposed[403]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Hypoaesthesia oral			
subjects affected / exposed[404]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed[405]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed[406]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lip dry			
subjects affected / exposed[407]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed[408]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed[409]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed[410]	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	0	1	2
Odynophagia			
subjects affected / exposed[411]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed[412]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Paraesthesia oral			
subjects affected / exposed[413]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed[414]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Proctitis			
subjects affected / exposed[415]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Rectal discharge			
subjects affected / exposed[416]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed[417]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal spasm			
subjects affected / exposed[418]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed[419]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retroperitoneal haemorrhage			
subjects affected / exposed[420]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed[421]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed[422]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed[423]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed[424]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed[425]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed[426]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed[427]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed[428]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed[429]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed[430]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed[431]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed[432]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed[433]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed[434]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatomyositis			
subjects affected / exposed[435]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed[436]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed[437]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed[438]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Eczema			
subjects affected / exposed[439]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed[440]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hirsutism			
subjects affected / exposed[441]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed[442]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed[443]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed[444]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed[445]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed[446]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed[447]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed[448]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed[449]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed[450]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Nail pigmentation			
subjects affected / exposed[451]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed[452]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed[453]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed[454]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed[455]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed[456]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed[457]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed[458]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed[459]	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
Pruritus allergic			
subjects affected / exposed[460]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed[461]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed[462]	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Rash macular			
subjects affected / exposed[463]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed[464]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed[465]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed[466]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed[467]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed[468]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed[469]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin erosion			
subjects affected / exposed[470]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed[471]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed[472]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed[473]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			

subjects affected / exposed[474]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed[475]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin reaction			
subjects affected / exposed[476]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed[477]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed[478]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trichorrhexis			
subjects affected / exposed[479]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed[480]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed[481]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Bladder irritation			
subjects affected / exposed[482]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed[483]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed[484]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed[485]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	3	0

Haematuria			
subjects affected / exposed[486]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed[487]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypertonic bladder			
subjects affected / exposed[488]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed[489]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed[490]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed[491]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed[492]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal infarct			
subjects affected / exposed[493]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal tubular necrosis			
subjects affected / exposed[494]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary fistula			
subjects affected / exposed[495]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed[496]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed[497]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urinary tract obstruction			
subjects affected / exposed[498]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed[499]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed[500]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed[501]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Euthyroid sick syndrome			
subjects affected / exposed[502]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed[503]	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Hypothyroidism			
subjects affected / exposed[504]	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Thyroid mass			
subjects affected / exposed[505]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed[506]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[507]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed[508]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Back pain			

subjects affected / exposed[509]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed[510]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed[511]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed[512]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed[513]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed[514]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed[515]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed[516]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed[517]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed[518]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed[519]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed[520]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed[521]	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed[522]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed[523]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed[524]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed[525]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome			
subjects affected / exposed[526]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed[527]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed[528]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed[529]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed[530]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Biliary tract infection			
subjects affected / exposed[531]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed[532]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed[533]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed[534]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed[535]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium bacteraemia			
subjects affected / exposed[536]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed[537]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed[538]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed[539]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis pseudomonal			
subjects affected / exposed[540]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed[541]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed[542]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed[543]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed[544]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Escherichia urinary tract infection			
subjects affected / exposed[545]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed[546]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed[547]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed[548]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed[549]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed[550]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed[551]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed[552]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed[553]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Keratitis viral			
subjects affected / exposed[554]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed[555]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed[556]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection			
subjects affected / exposed[557]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed[558]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed[559]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed[560]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed[561]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed[562]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed[563]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed[564]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed[565]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed[566]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed[567]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Penile infection			
subjects affected / exposed[568]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Peritonitis			
subjects affected / exposed[569]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed[570]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed[571]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed[572]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed[573]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed[574]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed[575]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed[576]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed[577]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed[578]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed[579]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Streptococcal infection			
subjects affected / exposed[580]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Tinea pedis			
subjects affected / exposed[581]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed[582]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed[583]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed[584]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed[585]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed[586]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection fungal			
subjects affected / exposed[587]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed[588]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Adult failure to thrive			
subjects affected / exposed[589]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed[590]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed[591]	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	2
Dehydration			

subjects affected / exposed[592]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrolyte imbalance			
subjects affected / exposed[593]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed[594]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed[595]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperamylasaemia			
subjects affected / exposed[596]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed[597]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed[598]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed[599]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed[600]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed[601]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed[602]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed[603]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			

subjects affected / exposed[604]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed[605]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed[606]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypervolaemia			
subjects affected / exposed[607]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed[608]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed[609]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed[610]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed[611]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed[612]	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed[613]	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed[614]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophagia			
subjects affected / exposed[615]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			

subjects affected / exposed[616]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed[617]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed[618]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed[619]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed[620]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed[621]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed[622]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed[623]	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (MSS-CRC)	Dose-escalation Cohort 5: Mona 750 mg Q4W + Durva	Dose-escalation Cohort 4: Mona 750 mg Q2W + Durva
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 40 (97.50%)	16 / 18 (88.89%)	18 / 18 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed[111]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed[112]	3 / 40 (7.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Malignant ascites			

subjects affected / exposed[113]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed[114]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed[115]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Tumour pain			
subjects affected / exposed[116]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed[117]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Embolism			
subjects affected / exposed[118]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed[119]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed[120]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed[121]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed[122]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed[123]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Jugular vein thrombosis			
subjects affected / exposed[124]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Lymphoedema			
subjects affected / exposed[125]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Orthostatic hypotension			
subjects affected / exposed[126]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed[127]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed[128]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed[129]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed[130]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed[131]	2 / 40 (5.00%)	5 / 18 (27.78%)	3 / 18 (16.67%)
occurrences (all)	3	5	4
Catheter site dermatitis			
subjects affected / exposed[132]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Catheter site erosion			
subjects affected / exposed[133]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed[134]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed[135]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Chest pain			

subjects affected / exposed[136]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed[137]	1 / 40 (2.50%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Complication associated with device			
subjects affected / exposed[138]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed[139]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed[140]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed[141]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed[142]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed[143]	7 / 40 (17.50%)	4 / 18 (22.22%)	2 / 18 (11.11%)
occurrences (all)	7	4	2
Gait disturbance			
subjects affected / exposed[144]	1 / 40 (2.50%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
General physical health deterioration			
subjects affected / exposed[145]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed[146]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed[147]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hernia pain			

subjects affected / exposed[148]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed[149]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Injection site discomfort			
subjects affected / exposed[150]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed[151]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed[152]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed[153]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Medical device pain			
subjects affected / exposed[154]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed[155]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed[156]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed[157]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed[158]	4 / 40 (10.00%)	2 / 18 (11.11%)	2 / 18 (11.11%)
occurrences (all)	4	4	2
Pain			
subjects affected / exposed[159]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			

subjects affected / exposed[160]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed[161]	8 / 40 (20.00%)	2 / 18 (11.11%)	3 / 18 (16.67%)
occurrences (all)	9	2	3
Secretion discharge			
subjects affected / exposed[162]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed[163]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Temperature regulation disorder			
subjects affected / exposed[164]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Xerosis			
subjects affected / exposed[165]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed[166]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed[167]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infusion related hypersensitivity reaction			
subjects affected / exposed[168]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed[169]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed[170]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Erectile dysfunction			

subjects affected / exposed[171]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Female genital tract fistula			
subjects affected / exposed[172]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Intermenstrual bleeding			
subjects affected / exposed[173]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Menstruation irregular			
subjects affected / exposed[174]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oedema genital			
subjects affected / exposed[175]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ovarian mass			
subjects affected / exposed[176]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed[177]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed[178]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Scrotal dermatitis			
subjects affected / exposed[179]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed[180]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Vaginal haemorrhage			
subjects affected / exposed[181]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Vulvovaginal discomfort			
subjects affected / exposed[182]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			

subjects affected / exposed[183]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed[184]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed[185]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed[186]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed[187]	5 / 40 (12.50%)	2 / 18 (11.11%)	2 / 18 (11.11%)
occurrences (all)	6	5	2
Dry throat			
subjects affected / exposed[188]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed[189]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed[190]	6 / 40 (15.00%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	6	0	2
Dyspnoea exertional			
subjects affected / exposed[191]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed[192]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed[193]	0 / 40 (0.00%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Hiccups			

subjects affected / exposed[194]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed[195]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed[196]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed[197]	3 / 40 (7.50%)	2 / 18 (11.11%)	0 / 18 (0.00%)
occurrences (all)	3	2	0
Nasal dryness			
subjects affected / exposed[198]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed[199]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
subjects affected / exposed[200]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed[201]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed[202]	2 / 40 (5.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Pleuritic pain			
subjects affected / exposed[203]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed[204]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed[205]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pulmonary embolism			

subjects affected / exposed[206]	1 / 40 (2.50%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Pulmonary haemorrhage			
subjects affected / exposed[207]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pulmonary pain			
subjects affected / exposed[208]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed[209]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed[210]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed[211]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Sinus pain			
subjects affected / exposed[212]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed[213]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tachypnoea			
subjects affected / exposed[214]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed[215]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed[216]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed[217]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Wheezing			

subjects affected / exposed[218]	4 / 40 (10.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed[219]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed[220]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed[221]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed[222]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed[223]	2 / 40 (5.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Hallucinations, mixed			
subjects affected / exposed[224]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed[225]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed[226]	5 / 40 (12.50%)	1 / 18 (5.56%)	2 / 18 (11.11%)
occurrences (all)	5	1	2
Irritability			
subjects affected / exposed[227]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed[228]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Mood swings			
subjects affected / exposed[229]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Nervousness			
subjects affected / exposed[230]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nightmare			
subjects affected / exposed[231]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion			
subjects affected / exposed[232]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed[233]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Alanine aminotransferase increased			
subjects affected / exposed[234]	2 / 40 (5.00%)	3 / 18 (16.67%)	1 / 18 (5.56%)
occurrences (all)	3	3	1
Amylase			
subjects affected / exposed[235]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed[236]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Aspartate aminotransferase increased			
subjects affected / exposed[237]	4 / 40 (10.00%)	3 / 18 (16.67%)	1 / 18 (5.56%)
occurrences (all)	4	3	2
Bacterial test positive			
subjects affected / exposed[238]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed[239]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed[240]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Blood bilirubin increased			

subjects affected / exposed[241]	2 / 40 (5.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Blood cholesterol increased			
subjects affected / exposed[242]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed[243]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed[244]	0 / 40 (0.00%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Blood fibrinogen increased			
subjects affected / exposed[245]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed[246]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed[247]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed[248]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed[249]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed[250]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Blood triglycerides increased			
subjects affected / exposed[251]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood uric acid decreased			

subjects affected / exposed[252]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Blood uric acid increased			
subjects affected / exposed[253]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Carbohydrate antigen 125 increased			
subjects affected / exposed[254]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed[255]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed[256]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed[257]	2 / 40 (5.00%)	2 / 18 (11.11%)	0 / 18 (0.00%)
occurrences (all)	2	2	0
General physical condition abnormal			
subjects affected / exposed[258]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed[259]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hepatic enzyme increased			
subjects affected / exposed[260]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed[261]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed[262]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			

subjects affected / exposed[263]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed[264]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed[265]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed[266]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Tri-iodothyronine free decreased			
subjects affected / exposed[267]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed[268]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed[269]	3 / 40 (7.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Weight increased			
subjects affected / exposed[270]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed[271]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed[272]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed[273]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed[274]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed[275]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed[276]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed[277]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed[278]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Muscle strain			
subjects affected / exposed[279]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail injury			
subjects affected / exposed[280]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed[281]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed[282]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed[283]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed[284]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed[285]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Stoma site discomfort			

subjects affected / exposed[286]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed[287]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed[288]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Wound dehiscence			
subjects affected / exposed[289]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed[290]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[291]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed[292]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed[293]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree			
subjects affected / exposed[294]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Bradycardia			
subjects affected / exposed[295]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cardiomegaly			
subjects affected / exposed[296]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Conduction disorder			
subjects affected / exposed[297]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Myocarditis			
subjects affected / exposed[298]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed[299]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed[300]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed[301]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed[302]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ventricular tachycardia			
subjects affected / exposed[303]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed[304]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed[305]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed[306]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed[307]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Central nervous system necrosis			
subjects affected / exposed[308]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cerebrospinal fluid leakage			

subjects affected / exposed[309]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cognitive disorder			
subjects affected / exposed[310]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Disturbance in attention			
subjects affected / exposed[311]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed[312]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Dysaesthesia			
subjects affected / exposed[313]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed[314]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed[315]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Encephalomalacia			
subjects affected / exposed[316]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed[317]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed[318]	7 / 40 (17.50%)	0 / 18 (0.00%)	3 / 18 (16.67%)
occurrences (all)	8	0	3
Hypersomnia			
subjects affected / exposed[319]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed[320]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lethargy			

subjects affected / exposed[321]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lhermitte's sign			
subjects affected / exposed[322]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed[323]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed[324]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolic encephalopathy			
subjects affected / exposed[325]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed[326]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed[327]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed[328]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Paraesthesia			
subjects affected / exposed[329]	1 / 40 (2.50%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Peripheral sensory neuropathy			
subjects affected / exposed[330]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed[331]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed[332]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed[333]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Speech disorder			
subjects affected / exposed[334]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed[335]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed[336]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed[337]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[338]	2 / 40 (5.00%)	1 / 18 (5.56%)	2 / 18 (11.11%)
occurrences (all)	2	1	2
Iron deficiency anaemia			
subjects affected / exposed[339]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed[340]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed[341]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed[342]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed[343]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed[344]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[345]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ear disorder			
subjects affected / exposed[346]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed[347]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ear pruritus			
subjects affected / exposed[348]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed[349]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Middle ear effusion			
subjects affected / exposed[350]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed[351]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed[352]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed[353]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed[354]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed[355]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			

subjects affected / exposed[356]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed[357]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed[358]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Eye discharge			
subjects affected / exposed[359]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed[360]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed[361]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed[362]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Eyelids pruritus			
subjects affected / exposed[363]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed[364]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed[365]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Periorbital oedema			
subjects affected / exposed[366]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed[367]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pterygium			

subjects affected / exposed[368]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed[369]	3 / 40 (7.50%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	3	0	3
Visual impairment			
subjects affected / exposed[370]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed[371]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed[372]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed[373]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Abdominal hernia			
subjects affected / exposed[374]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed[375]	10 / 40 (25.00%)	3 / 18 (16.67%)	2 / 18 (11.11%)
occurrences (all)	10	3	2
Abdominal pain lower			
subjects affected / exposed[376]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed[377]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Abdominal rigidity			
subjects affected / exposed[378]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Anal haemorrhage			
subjects affected / exposed[379]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Anal incontinence			
subjects affected / exposed[380]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed[381]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed[382]	3 / 40 (7.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	3	1	0
Autoimmune pancreatitis			
subjects affected / exposed[383]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed[384]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed[385]	7 / 40 (17.50%)	2 / 18 (11.11%)	9 / 18 (50.00%)
occurrences (all)	8	2	9
Defaecation urgency			
subjects affected / exposed[386]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed[387]	6 / 40 (15.00%)	2 / 18 (11.11%)	5 / 18 (27.78%)
occurrences (all)	6	2	5
Dry mouth			
subjects affected / exposed[388]	1 / 40 (2.50%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Dyspepsia			
subjects affected / exposed[389]	4 / 40 (10.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Dysphagia			
subjects affected / exposed[390]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Epigastric discomfort			
subjects affected / exposed[391]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Eructation			
subjects affected / exposed[392]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed[393]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Food poisoning			
subjects affected / exposed[394]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Frequent bowel movements			
subjects affected / exposed[395]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed[396]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed[397]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed[398]	2 / 40 (5.00%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	2	1	1
Glossodynia			
subjects affected / exposed[399]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed[400]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed[401]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed[402]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia teeth			
subjects affected / exposed[403]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Hypoaesthesia oral			
subjects affected / exposed[404]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed[405]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed[406]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed[407]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed[408]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed[409]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed[410]	9 / 40 (22.50%)	4 / 18 (22.22%)	4 / 18 (22.22%)
occurrences (all)	10	4	7
Odynophagia			
subjects affected / exposed[411]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed[412]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed[413]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed[414]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed[415]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0

Rectal discharge			
subjects affected / exposed[416]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed[417]	0 / 40 (0.00%)	2 / 18 (11.11%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Rectal spasm			
subjects affected / exposed[418]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed[419]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Retroperitoneal haemorrhage			
subjects affected / exposed[420]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed[421]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed[422]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Toothache			
subjects affected / exposed[423]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed[424]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed[425]	8 / 40 (20.00%)	1 / 18 (5.56%)	5 / 18 (27.78%)
occurrences (all)	13	1	9
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed[426]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed[427]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed[428]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Jaundice			
subjects affected / exposed[429]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed[430]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed[431]	0 / 40 (0.00%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Blister			
subjects affected / exposed[432]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed[433]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed[434]	2 / 40 (5.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Dermatomyositis			
subjects affected / exposed[435]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed[436]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed[437]	1 / 40 (2.50%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Ecchymosis			
subjects affected / exposed[438]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Eczema			
subjects affected / exposed[439]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed[440]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hirsutism			
subjects affected / exposed[441]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed[442]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed[443]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed[444]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed[445]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed[446]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed[447]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed[448]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed[449]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed[450]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Nail pigmentation			
subjects affected / exposed[451]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed[452]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed[453]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed[454]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed[455]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed[456]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed[457]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed[458]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed[459]	7 / 40 (17.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	7	0	0
Pruritus allergic			
subjects affected / exposed[460]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed[461]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed[462]	5 / 40 (12.50%)	4 / 18 (22.22%)	0 / 18 (0.00%)
occurrences (all)	5	4	0
Rash macular			
subjects affected / exposed[463]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed[464]	3 / 40 (7.50%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	3	0	2
Rash pruritic			
subjects affected / exposed[465]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed[466]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed[467]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed[468]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed[469]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin erosion			
subjects affected / exposed[470]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed[471]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed[472]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed[473]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin lesion			

subjects affected / exposed[474]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed[475]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin reaction			
subjects affected / exposed[476]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin toxicity			
subjects affected / exposed[477]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed[478]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Trichorrhexis			
subjects affected / exposed[479]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed[480]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed[481]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bladder irritation			
subjects affected / exposed[482]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed[483]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed[484]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Dysuria			
subjects affected / exposed[485]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1

Haematuria			
subjects affected / exposed[486]	1 / 40 (2.50%)	1 / 18 (5.56%)	4 / 18 (22.22%)
occurrences (all)	1	1	4
Hydronephrosis			
subjects affected / exposed[487]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			
subjects affected / exposed[488]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed[489]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed[490]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed[491]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed[492]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal infarct			
subjects affected / exposed[493]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal tubular necrosis			
subjects affected / exposed[494]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urinary fistula			
subjects affected / exposed[495]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed[496]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed[497]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0

Urinary tract obstruction			
subjects affected / exposed[498]	0 / 40 (0.00%)	1 / 18 (5.56%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Urinary tract pain			
subjects affected / exposed[499]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Urine flow decreased			
subjects affected / exposed[500]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed[501]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Euthyroid sick syndrome			
subjects affected / exposed[502]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed[503]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Hypothyroidism			
subjects affected / exposed[504]	4 / 40 (10.00%)	2 / 18 (11.11%)	1 / 18 (5.56%)
occurrences (all)	4	2	1
Thyroid mass			
subjects affected / exposed[505]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed[506]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[507]	6 / 40 (15.00%)	4 / 18 (22.22%)	3 / 18 (16.67%)
occurrences (all)	7	5	4
Arthritis			
subjects affected / exposed[508]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed[509]	6 / 40 (15.00%)	2 / 18 (11.11%)	1 / 18 (5.56%)
occurrences (all)	6	3	1
Bone pain			
subjects affected / exposed[510]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed[511]	1 / 40 (2.50%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Gouty arthritis			
subjects affected / exposed[512]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed[513]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed[514]	1 / 40 (2.50%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Muscular weakness			
subjects affected / exposed[515]	1 / 40 (2.50%)	0 / 18 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Musculoskeletal chest pain			
subjects affected / exposed[516]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed[517]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed[518]	2 / 40 (5.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
Myalgia			
subjects affected / exposed[519]	4 / 40 (10.00%)	1 / 18 (5.56%)	2 / 18 (11.11%)
occurrences (all)	4	1	2
Neck mass			
subjects affected / exposed[520]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed[521]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed[522]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed[523]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed[524]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Spondylitis			
subjects affected / exposed[525]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome			
subjects affected / exposed[526]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed[527]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Abscess			
subjects affected / exposed[528]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed[529]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed[530]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Biliary tract infection			
subjects affected / exposed[531]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed[532]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Bronchitis			
subjects affected / exposed[533]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed[534]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed[535]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Clostridium bacteraemia			
subjects affected / exposed[536]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed[537]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed[538]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed[539]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cystitis pseudomonal			
subjects affected / exposed[540]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed[541]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Diverticulitis			
subjects affected / exposed[542]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed[543]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed[544]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Escherichia urinary tract infection			
subjects affected / exposed[545]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed[546]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed[547]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed[548]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed[549]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed[550]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hordeolum			
subjects affected / exposed[551]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed[552]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed[553]	3 / 40 (7.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Keratitis viral			
subjects affected / exposed[554]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed[555]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed[556]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection			
subjects affected / exposed[557]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Medical device site infection			
subjects affected / exposed[558]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed[559]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed[560]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed[561]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed[562]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed[563]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed[564]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed[565]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed[566]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed[567]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Penile infection			
subjects affected / exposed[568]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Peritonitis			
subjects affected / exposed[569]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed[570]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed[571]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed[572]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed[573]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed[574]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed[575]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed[576]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed[577]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed[578]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed[579]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Streptococcal infection			
subjects affected / exposed[580]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Tinea pedis			
subjects affected / exposed[581]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed[582]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed[583]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed[584]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed[585]	1 / 40 (2.50%)	1 / 18 (5.56%)	2 / 18 (11.11%)
occurrences (all)	1	1	4
Urinary tract infection			
subjects affected / exposed[586]	1 / 40 (2.50%)	2 / 18 (11.11%)	1 / 18 (5.56%)
occurrences (all)	1	3	1
Urinary tract infection fungal			
subjects affected / exposed[587]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vaginal infection			
subjects affected / exposed[588]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Adult failure to thrive			
subjects affected / exposed[589]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed[590]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed[591]	7 / 40 (17.50%)	4 / 18 (22.22%)	4 / 18 (22.22%)
occurrences (all)	9	4	4
Dehydration			

subjects affected / exposed[592]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Electrolyte imbalance			
subjects affected / exposed[593]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed[594]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed[595]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperamylasaemia			
subjects affected / exposed[596]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed[597]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed[598]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hypercreatininaemia			
subjects affected / exposed[599]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed[600]	1 / 40 (2.50%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Hyperkalaemia			
subjects affected / exposed[601]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperlipasaemia			
subjects affected / exposed[602]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypermagnesaemia			
subjects affected / exposed[603]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			

subjects affected / exposed[604]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed[605]	1 / 40 (2.50%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed[606]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hypervolaemia			
subjects affected / exposed[607]	0 / 40 (0.00%)	1 / 18 (5.56%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed[608]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed[609]	0 / 40 (0.00%)	0 / 18 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypochloraemia			
subjects affected / exposed[610]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed[611]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed[612]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed[613]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed[614]	2 / 40 (5.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hypophagia			
subjects affected / exposed[615]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			

subjects affected / exposed[616]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed[617]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed[618]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed[619]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed[620]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed[621]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed[622]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed[623]	0 / 40 (0.00%)	0 / 18 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Exploration Cohort C1A: Mona 750 mg Q2W + Durva + Cetu	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (NSCLC)	Exploration CohortA1: Mona 750 mg Q2W+Durva + mFOLFOX6 + Beva
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 40 (97.50%)	20 / 20 (100.00%)	18 / 18 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed[111]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed[112]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malignant ascites			

subjects affected / exposed[113]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed[114]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Tumour associated fever			
subjects affected / exposed[115]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed[116]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed[117]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed[118]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed[119]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed[120]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed[121]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed[122]	0 / 39 (0.00%)	0 / 20 (0.00%)	4 / 18 (22.22%)
occurrences (all)	0	0	6
Hypotension			
subjects affected / exposed[123]	1 / 39 (2.56%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	1	0	3
Jugular vein thrombosis			
subjects affected / exposed[124]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Lymphoedema			
subjects affected / exposed[125]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed[126]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Thrombosis			
subjects affected / exposed[127]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed[128]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed[129]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed[130]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed[131]	2 / 39 (5.13%)	10 / 20 (50.00%)	1 / 18 (5.56%)
occurrences (all)	3	21	1
Catheter site dermatitis			
subjects affected / exposed[132]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Catheter site erosion			
subjects affected / exposed[133]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Catheter site pain			
subjects affected / exposed[134]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed[135]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed[136]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed[137]	5 / 39 (12.82%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	5	0	3
Complication associated with device			
subjects affected / exposed[138]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cyst			
subjects affected / exposed[139]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed[140]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed[141]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed[142]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed[143]	14 / 39 (35.90%)	1 / 20 (5.00%)	14 / 18 (77.78%)
occurrences (all)	20	1	33
Gait disturbance			
subjects affected / exposed[144]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed[145]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed[146]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed[147]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hernia pain			

subjects affected / exposed[148]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed[149]	4 / 39 (10.26%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	4	0	2
Injection site discomfort			
subjects affected / exposed[150]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed[151]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed[152]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed[153]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Medical device pain			
subjects affected / exposed[154]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed[155]	1 / 39 (2.56%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	1	0	4
Non-cardiac chest pain			
subjects affected / exposed[156]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed[157]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed[158]	3 / 39 (7.69%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	4	0	2
Pain			
subjects affected / exposed[159]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			

subjects affected / exposed[160]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed[161]	14 / 39 (35.90%)	2 / 20 (10.00%)	6 / 18 (33.33%)
occurrences (all)	17	2	9
Secretion discharge			
subjects affected / exposed[162]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Temperature intolerance			
subjects affected / exposed[163]	0 / 39 (0.00%)	0 / 20 (0.00%)	7 / 18 (38.89%)
occurrences (all)	0	0	7
Temperature regulation disorder			
subjects affected / exposed[164]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed[165]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed[166]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Drug hypersensitivity			
subjects affected / exposed[167]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Infusion related hypersensitivity reaction			
subjects affected / exposed[168]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Seasonal allergy			
subjects affected / exposed[169]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed[170]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			

subjects affected / exposed[171]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Female genital tract fistula			
subjects affected / exposed[172]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed[173]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed[174]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed[175]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ovarian mass			
subjects affected / exposed[176]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed[177]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Postmenopausal haemorrhage			
subjects affected / exposed[178]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Scrotal dermatitis			
subjects affected / exposed[179]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vaginal discharge			
subjects affected / exposed[180]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed[181]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Vulvovaginal discomfort			
subjects affected / exposed[182]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			

subjects affected / exposed[183]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed[184]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed[185]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed[186]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Cough			
subjects affected / exposed[187]	5 / 39 (12.82%)	9 / 20 (45.00%)	2 / 18 (11.11%)
occurrences (all)	7	10	3
Dry throat			
subjects affected / exposed[188]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed[189]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed[190]	5 / 39 (12.82%)	6 / 20 (30.00%)	5 / 18 (27.78%)
occurrences (all)	6	6	12
Dyspnoea exertional			
subjects affected / exposed[191]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed[192]	0 / 39 (0.00%)	0 / 20 (0.00%)	5 / 18 (27.78%)
occurrences (all)	0	0	7
Haemoptysis			
subjects affected / exposed[193]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hiccups			

subjects affected / exposed[194]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed[195]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed[196]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed[197]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Nasal dryness			
subjects affected / exposed[198]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed[199]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
subjects affected / exposed[200]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed[201]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed[202]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pleuritic pain			
subjects affected / exposed[203]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed[204]	0 / 39 (0.00%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Productive cough			
subjects affected / exposed[205]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pulmonary embolism			

subjects affected / exposed[206]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Pulmonary haemorrhage			
subjects affected / exposed[207]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pulmonary pain			
subjects affected / exposed[208]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed[209]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed[210]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed[211]	0 / 39 (0.00%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	3
Sinus pain			
subjects affected / exposed[212]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Sleep apnoea syndrome			
subjects affected / exposed[213]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed[214]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed[215]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Throat tightness			
subjects affected / exposed[216]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed[217]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Wheezing			

subjects affected / exposed[218]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed[219]	2 / 39 (5.13%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	2	0	2
Confusional state			
subjects affected / exposed[220]	2 / 39 (5.13%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Delirium			
subjects affected / exposed[221]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed[222]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed[223]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hallucinations, mixed			
subjects affected / exposed[224]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed[225]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed[226]	3 / 39 (7.69%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	3	0	6
Irritability			
subjects affected / exposed[227]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed[228]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Mood swings			
subjects affected / exposed[229]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Nervousness			
subjects affected / exposed[230]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed[231]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Product issues			
Device occlusion			
subjects affected / exposed[232]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed[233]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed[234]	2 / 39 (5.13%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	2	0	2
Amylase			
subjects affected / exposed[235]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed[236]	3 / 39 (7.69%)	0 / 20 (0.00%)	4 / 18 (22.22%)
occurrences (all)	3	0	7
Aspartate aminotransferase increased			
subjects affected / exposed[237]	6 / 39 (15.38%)	0 / 20 (0.00%)	5 / 18 (27.78%)
occurrences (all)	6	0	6
Bacterial test positive			
subjects affected / exposed[238]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed[239]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed[240]	3 / 39 (7.69%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	3	0	3
Blood bilirubin increased			

subjects affected / exposed[241]	4 / 39 (10.26%)	0 / 20 (0.00%)	4 / 18 (22.22%)
occurrences (all)	7	0	4
Blood cholesterol increased			
subjects affected / exposed[242]	2 / 39 (5.13%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Blood creatine increased			
subjects affected / exposed[243]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed[244]	3 / 39 (7.69%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Blood fibrinogen increased			
subjects affected / exposed[245]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed[246]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed[247]	2 / 39 (5.13%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Blood magnesium decreased			
subjects affected / exposed[248]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed[249]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed[250]	0 / 39 (0.00%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Blood triglycerides increased			
subjects affected / exposed[251]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Blood uric acid decreased			

subjects affected / exposed[252]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed[253]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Carbohydrate antigen 125 increased			
subjects affected / exposed[254]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed[255]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed[256]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed[257]	2 / 39 (5.13%)	1 / 20 (5.00%)	3 / 18 (16.67%)
occurrences (all)	2	1	3
General physical condition abnormal			
subjects affected / exposed[258]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed[259]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed[260]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed[261]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed[262]	2 / 39 (5.13%)	1 / 20 (5.00%)	4 / 18 (22.22%)
occurrences (all)	2	1	6
Lymphocyte count decreased			

subjects affected / exposed[263]	1 / 39 (2.56%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Neutrophil count decreased			
subjects affected / exposed[264]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	3
Platelet count decreased			
subjects affected / exposed[265]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Transaminases increased			
subjects affected / exposed[266]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed[267]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Urine leukocyte esterase positive			
subjects affected / exposed[268]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed[269]	1 / 39 (2.56%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	1	0	3
Weight increased			
subjects affected / exposed[270]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed[271]	0 / 39 (0.00%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	4
White blood cells urine positive			
subjects affected / exposed[272]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed[273]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Ankle fracture			

subjects affected / exposed[274]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed[275]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed[276]	1 / 39 (2.56%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Fall			
subjects affected / exposed[277]	0 / 39 (0.00%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	3
Infusion related reaction			
subjects affected / exposed[278]	2 / 39 (5.13%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	3	0	2
Muscle strain			
subjects affected / exposed[279]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail injury			
subjects affected / exposed[280]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed[281]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed[282]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed[283]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed[284]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Spinal fracture			
subjects affected / exposed[285]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Stoma site discomfort			

subjects affected / exposed[286]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Stoma site pain			
subjects affected / exposed[287]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed[288]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed[289]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed[290]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[291]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed[292]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed[293]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree			
subjects affected / exposed[294]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed[295]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed[296]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Conduction disorder			
subjects affected / exposed[297]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Myocarditis			
subjects affected / exposed[298]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed[299]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pericardial effusion			
subjects affected / exposed[300]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed[301]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed[302]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ventricular tachycardia			
subjects affected / exposed[303]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed[304]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed[305]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed[306]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed[307]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Central nervous system necrosis			
subjects affected / exposed[308]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cerebrospinal fluid leakage			

subjects affected / exposed[309]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed[310]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed[311]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed[312]	2 / 39 (5.13%)	1 / 20 (5.00%)	6 / 18 (33.33%)
occurrences (all)	2	1	7
Dysaesthesia			
subjects affected / exposed[313]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed[314]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed[315]	0 / 39 (0.00%)	0 / 20 (0.00%)	5 / 18 (27.78%)
occurrences (all)	0	0	5
Encephalomalacia			
subjects affected / exposed[316]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Facial paralysis			
subjects affected / exposed[317]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed[318]	8 / 39 (20.51%)	1 / 20 (5.00%)	6 / 18 (33.33%)
occurrences (all)	9	1	7
Hypersomnia			
subjects affected / exposed[319]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed[320]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Lethargy			

subjects affected / exposed[321]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lhermitte's sign			
subjects affected / exposed[322]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed[323]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed[324]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Metabolic encephalopathy			
subjects affected / exposed[325]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed[326]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Neuralgia			
subjects affected / exposed[327]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed[328]	1 / 39 (2.56%)	0 / 20 (0.00%)	10 / 18 (55.56%)
occurrences (all)	1	0	12
Paraesthesia			
subjects affected / exposed[329]	0 / 39 (0.00%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	4
Peripheral sensory neuropathy			
subjects affected / exposed[330]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed[331]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Seizure			
subjects affected / exposed[332]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed[333]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Speech disorder			
subjects affected / exposed[334]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed[335]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Taste disorder			
subjects affected / exposed[336]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed[337]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[338]	6 / 39 (15.38%)	1 / 20 (5.00%)	3 / 18 (16.67%)
occurrences (all)	7	1	7
Iron deficiency anaemia			
subjects affected / exposed[339]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed[340]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Lymphadenopathy			
subjects affected / exposed[341]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed[342]	0 / 39 (0.00%)	0 / 20 (0.00%)	8 / 18 (44.44%)
occurrences (all)	0	0	15
Thrombocytopenia			
subjects affected / exposed[343]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed[344]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[345]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed[346]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed[347]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed[348]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed[349]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Middle ear effusion			
subjects affected / exposed[350]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed[351]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed[352]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed[353]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed[354]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blepharospasm			
subjects affected / exposed[355]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			

subjects affected / exposed[356]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed[357]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed[358]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Eye discharge			
subjects affected / exposed[359]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed[360]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed[361]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Eye pruritus			
subjects affected / exposed[362]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed[363]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed[364]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed[365]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed[366]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed[367]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pterygium			

subjects affected / exposed[368]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed[369]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed[370]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed[371]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed[372]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed[373]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Abdominal hernia			
subjects affected / exposed[374]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed[375]	5 / 39 (12.82%)	0 / 20 (0.00%)	4 / 18 (22.22%)
occurrences (all)	5	0	4
Abdominal pain lower			
subjects affected / exposed[376]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Abdominal pain upper			
subjects affected / exposed[377]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	4
Abdominal rigidity			
subjects affected / exposed[378]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Anal haemorrhage			
subjects affected / exposed[379]	2 / 39 (5.13%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0

Anal incontinence			
subjects affected / exposed[380]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Anorectal discomfort			
subjects affected / exposed[381]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed[382]	2 / 39 (5.13%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Autoimmune pancreatitis			
subjects affected / exposed[383]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed[384]	0 / 39 (0.00%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed[385]	4 / 39 (10.26%)	2 / 20 (10.00%)	5 / 18 (27.78%)
occurrences (all)	5	2	5
Defaecation urgency			
subjects affected / exposed[386]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed[387]	5 / 39 (12.82%)	6 / 20 (30.00%)	8 / 18 (44.44%)
occurrences (all)	8	7	24
Dry mouth			
subjects affected / exposed[388]	1 / 39 (2.56%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	1	1	1
Dyspepsia			
subjects affected / exposed[389]	0 / 39 (0.00%)	1 / 20 (5.00%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Dysphagia			
subjects affected / exposed[390]	0 / 39 (0.00%)	2 / 20 (10.00%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Epigastric discomfort			
subjects affected / exposed[391]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1

Eructation			
subjects affected / exposed[392]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed[393]	1 / 39 (2.56%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Food poisoning			
subjects affected / exposed[394]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed[395]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed[396]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed[397]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed[398]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Glossodynia			
subjects affected / exposed[399]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed[400]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal haemorrhage			
subjects affected / exposed[401]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed[402]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Hyperaesthesia teeth			
subjects affected / exposed[403]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Hypoaesthesia oral			
subjects affected / exposed[404]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ileus			
subjects affected / exposed[405]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed[406]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed[407]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed[408]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Melaena			
subjects affected / exposed[409]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed[410]	9 / 39 (23.08%)	3 / 20 (15.00%)	12 / 18 (66.67%)
occurrences (all)	12	4	26
Odynophagia			
subjects affected / exposed[411]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed[412]	1 / 39 (2.56%)	0 / 20 (0.00%)	6 / 18 (33.33%)
occurrences (all)	1	0	6
Paraesthesia oral			
subjects affected / exposed[413]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed[414]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed[415]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Rectal discharge			
subjects affected / exposed[416]	1 / 39 (2.56%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Rectal haemorrhage			
subjects affected / exposed[417]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rectal spasm			
subjects affected / exposed[418]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Rectal tenesmus			
subjects affected / exposed[419]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Retroperitoneal haemorrhage			
subjects affected / exposed[420]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed[421]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed[422]	3 / 39 (7.69%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	3	0	3
Toothache			
subjects affected / exposed[423]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed[424]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed[425]	7 / 39 (17.95%)	4 / 20 (20.00%)	7 / 18 (38.89%)
occurrences (all)	9	4	8
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed[426]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed[427]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
Hypertransaminasaemia			
subjects affected / exposed[428]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Jaundice			
subjects affected / exposed[429]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed[430]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed[431]	0 / 39 (0.00%)	0 / 20 (0.00%)	6 / 18 (33.33%)
occurrences (all)	0	0	7
Blister			
subjects affected / exposed[432]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed[433]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed[434]	20 / 39 (51.28%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	21	0	1
Dermatomyositis			
subjects affected / exposed[435]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed[436]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed[437]	2 / 39 (5.13%)	1 / 20 (5.00%)	2 / 18 (11.11%)
occurrences (all)	2	1	2
Ecchymosis			
subjects affected / exposed[438]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Eczema			
subjects affected / exposed[439]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed[440]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hirsutism			
subjects affected / exposed[441]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed[442]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertrichosis			
subjects affected / exposed[443]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed[444]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed[445]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lichen planus			
subjects affected / exposed[446]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Madarosis			
subjects affected / exposed[447]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed[448]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Nail discolouration			
subjects affected / exposed[449]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed[450]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Nail pigmentation			
subjects affected / exposed[451]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed[452]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Onychalgia			
subjects affected / exposed[453]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed[454]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed[455]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed[456]	1 / 39 (2.56%)	0 / 20 (0.00%)	4 / 18 (22.22%)
occurrences (all)	1	0	4
Petechiae			
subjects affected / exposed[457]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Photosensitivity reaction			
subjects affected / exposed[458]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed[459]	6 / 39 (15.38%)	1 / 20 (5.00%)	3 / 18 (16.67%)
occurrences (all)	6	1	3
Pruritus allergic			
subjects affected / exposed[460]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed[461]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed[462]	12 / 39 (30.77%)	1 / 20 (5.00%)	3 / 18 (16.67%)
occurrences (all)	14	1	3
Rash macular			
subjects affected / exposed[463]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed[464]	6 / 39 (15.38%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	6	0	1
Rash pruritic			
subjects affected / exposed[465]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed[466]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed[467]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed[468]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed[469]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin erosion			
subjects affected / exposed[470]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed[471]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin fissures			
subjects affected / exposed[472]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin hyperpigmentation			
subjects affected / exposed[473]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	2
Skin lesion			

subjects affected / exposed[474]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin mass			
subjects affected / exposed[475]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin reaction			
subjects affected / exposed[476]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed[477]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed[478]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Trichorrhexis			
subjects affected / exposed[479]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed[480]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed[481]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Bladder irritation			
subjects affected / exposed[482]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed[483]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed[484]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed[485]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Haematuria			
subjects affected / exposed[486]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hydronephrosis			
subjects affected / exposed[487]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertonic bladder			
subjects affected / exposed[488]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed[489]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed[490]	2 / 39 (5.13%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Proteinuria			
subjects affected / exposed[491]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Renal failure			
subjects affected / exposed[492]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Renal infarct			
subjects affected / exposed[493]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Renal tubular necrosis			
subjects affected / exposed[494]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urinary fistula			
subjects affected / exposed[495]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed[496]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed[497]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Urinary tract obstruction			
subjects affected / exposed[498]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Urinary tract pain			
subjects affected / exposed[499]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed[500]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed[501]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Euthyroid sick syndrome			
subjects affected / exposed[502]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed[503]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed[504]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Thyroid mass			
subjects affected / exposed[505]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed[506]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[507]	2 / 39 (5.13%)	3 / 20 (15.00%)	2 / 18 (11.11%)
occurrences (all)	3	3	5
Arthritis			
subjects affected / exposed[508]	0 / 39 (0.00%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	0	1	16
Back pain			

subjects affected / exposed[509]	4 / 39 (10.26%)	1 / 20 (5.00%)	3 / 18 (16.67%)
occurrences (all)	4	1	4
Bone pain			
subjects affected / exposed[510]	0 / 39 (0.00%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Flank pain			
subjects affected / exposed[511]	1 / 39 (2.56%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Gouty arthritis			
subjects affected / exposed[512]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed[513]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed[514]	0 / 39 (0.00%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	5
Muscular weakness			
subjects affected / exposed[515]	1 / 39 (2.56%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	1	0	5
Musculoskeletal chest pain			
subjects affected / exposed[516]	0 / 39 (0.00%)	3 / 20 (15.00%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal discomfort			
subjects affected / exposed[517]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed[518]	0 / 39 (0.00%)	4 / 20 (20.00%)	0 / 18 (0.00%)
occurrences (all)	0	4	0
Myalgia			
subjects affected / exposed[519]	6 / 39 (15.38%)	2 / 20 (10.00%)	2 / 18 (11.11%)
occurrences (all)	6	3	3
Neck mass			
subjects affected / exposed[520]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neck pain			

subjects affected / exposed[521]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed[522]	1 / 39 (2.56%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Pain in jaw			
subjects affected / exposed[523]	0 / 39 (0.00%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	3
Sacral pain			
subjects affected / exposed[524]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed[525]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	4
Temporomandibular joint syndrome			
subjects affected / exposed[526]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed[527]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed[528]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed[529]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed[530]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Biliary tract infection			
subjects affected / exposed[531]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed[532]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed[533]	0 / 39 (0.00%)	2 / 20 (10.00%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Candida infection			
subjects affected / exposed[534]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed[535]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Clostridium bacteraemia			
subjects affected / exposed[536]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed[537]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed[538]	2 / 39 (5.13%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Cystitis			
subjects affected / exposed[539]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cystitis pseudomonal			
subjects affected / exposed[540]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed[541]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Diverticulitis			
subjects affected / exposed[542]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Enterocolitis infectious			
subjects affected / exposed[543]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Escherichia sepsis			
subjects affected / exposed[544]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Escherichia urinary tract infection			
subjects affected / exposed[545]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Eye infection			
subjects affected / exposed[546]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed[547]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed[548]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed[549]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed[550]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed[551]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed[552]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed[553]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Keratitis viral			
subjects affected / exposed[554]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed[555]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed[556]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection			
subjects affected / exposed[557]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed[558]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed[559]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed[560]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed[561]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed[562]	1 / 39 (2.56%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Oral fungal infection			
subjects affected / exposed[563]	0 / 39 (0.00%)	2 / 20 (10.00%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Oral herpes			
subjects affected / exposed[564]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed[565]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed[566]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed[567]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Penile infection			
subjects affected / exposed[568]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Peritonitis			
subjects affected / exposed[569]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed[570]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed[571]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pyuria			
subjects affected / exposed[572]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed[573]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed[574]	0 / 39 (0.00%)	3 / 20 (15.00%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Rhinitis			
subjects affected / exposed[575]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed[576]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed[577]	0 / 39 (0.00%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	3
Staphylococcal infection			
subjects affected / exposed[578]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed[579]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Streptococcal infection			
subjects affected / exposed[580]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Tinea pedis			
subjects affected / exposed[581]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed[582]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed[583]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed[584]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed[585]	2 / 39 (5.13%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Urinary tract infection			
subjects affected / exposed[586]	3 / 39 (7.69%)	0 / 20 (0.00%)	4 / 18 (22.22%)
occurrences (all)	3	0	6
Urinary tract infection fungal			
subjects affected / exposed[587]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed[588]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Adult failure to thrive			
subjects affected / exposed[589]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cachexia			
subjects affected / exposed[590]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed[591]	10 / 39 (25.64%)	3 / 20 (15.00%)	8 / 18 (44.44%)
occurrences (all)	11	3	11
Dehydration			

subjects affected / exposed[592]	2 / 39 (5.13%)	0 / 20 (0.00%)	4 / 18 (22.22%)
occurrences (all)	2	0	4
Electrolyte imbalance			
subjects affected / exposed[593]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed[594]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Gout			
subjects affected / exposed[595]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hyperamylasaemia			
subjects affected / exposed[596]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed[597]	0 / 39 (0.00%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed[598]	0 / 39 (0.00%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hypercreatininaemia			
subjects affected / exposed[599]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed[600]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed[601]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hyperlipasaemia			
subjects affected / exposed[602]	1 / 39 (2.56%)	1 / 20 (5.00%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Hypermagnesaemia			
subjects affected / exposed[603]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			

subjects affected / exposed[604]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed[605]	1 / 39 (2.56%)	1 / 20 (5.00%)	1 / 18 (5.56%)
occurrences (all)	2	2	1
Hyperuricaemia			
subjects affected / exposed[606]	2 / 39 (5.13%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hypervolaemia			
subjects affected / exposed[607]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed[608]	2 / 39 (5.13%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	2	0	2
Hypocalcaemia			
subjects affected / exposed[609]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed[610]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed[611]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed[612]	2 / 39 (5.13%)	0 / 20 (0.00%)	3 / 18 (16.67%)
occurrences (all)	2	0	3
Hypomagnesaemia			
subjects affected / exposed[613]	3 / 39 (7.69%)	0 / 20 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1
Hyponatraemia			
subjects affected / exposed[614]	2 / 39 (5.13%)	0 / 20 (0.00%)	2 / 18 (11.11%)
occurrences (all)	3	0	3
Hypophagia			
subjects affected / exposed[615]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			

subjects affected / exposed[616]	1 / 39 (2.56%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed[617]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed[618]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed[619]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed[620]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed[621]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed[622]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed[623]	0 / 39 (0.00%)	0 / 20 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Exploration CohortA2: Mona 750 mg Q2W+Durva+mFOLFOX6+Cetu	Dose-expansion Cohort: Mona 750 mg Q2W+Durva (Endometrial MSS)	Dose-expansion Cohort: Mona 750 mg Q2W + Durva (ovarian)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 18 (100.00%)	39 / 40 (97.50%)	40 / 40 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed[111]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed[112]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0

Malignant ascites			
subjects affected / exposed[113]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Squamous cell carcinoma			
subjects affected / exposed[114]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed[115]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed[116]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed[117]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	1	2	1
Embolism			
subjects affected / exposed[118]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed[119]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed[120]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed[121]	0 / 18 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Hypertension			
subjects affected / exposed[122]	1 / 18 (5.56%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	2	0	1
Hypotension			
subjects affected / exposed[123]	2 / 18 (11.11%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	2	1	1
Jugular vein thrombosis			

subjects affected / exposed[124]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed[125]	0 / 18 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Orthostatic hypotension			
subjects affected / exposed[126]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed[127]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed[128]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed[129]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Adverse drug reaction			
subjects affected / exposed[130]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed[131]	1 / 18 (5.56%)	2 / 40 (5.00%)	12 / 40 (30.00%)
occurrences (all)	1	3	13
Catheter site dermatitis			
subjects affected / exposed[132]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Catheter site erosion			
subjects affected / exposed[133]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed[134]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Chest discomfort			

subjects affected / exposed[135]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed[136]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed[137]	1 / 18 (5.56%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	1	3	0
Complication associated with device			
subjects affected / exposed[138]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed[139]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed[140]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Early satiety			
subjects affected / exposed[141]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Facial pain			
subjects affected / exposed[142]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed[143]	7 / 18 (38.89%)	20 / 40 (50.00%)	11 / 40 (27.50%)
occurrences (all)	9	22	11
Gait disturbance			
subjects affected / exposed[144]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed[145]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed[146]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Hernia			

subjects affected / exposed[147]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hernia pain			
subjects affected / exposed[148]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed[149]	2 / 18 (11.11%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Injection site discomfort			
subjects affected / exposed[150]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed[151]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed[152]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed[153]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Medical device pain			
subjects affected / exposed[154]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed[155]	1 / 18 (5.56%)	1 / 40 (2.50%)	3 / 40 (7.50%)
occurrences (all)	1	1	3
Non-cardiac chest pain			
subjects affected / exposed[156]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Oedema			
subjects affected / exposed[157]	0 / 18 (0.00%)	1 / 40 (2.50%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
Oedema peripheral			
subjects affected / exposed[158]	0 / 18 (0.00%)	3 / 40 (7.50%)	4 / 40 (10.00%)
occurrences (all)	0	3	4
Pain			

subjects affected / exposed[159]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed[160]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed[161]	4 / 18 (22.22%)	6 / 40 (15.00%)	8 / 40 (20.00%)
occurrences (all)	4	6	12
Secretion discharge			
subjects affected / exposed[162]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed[163]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Temperature regulation disorder			
subjects affected / exposed[164]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Xerosis			
subjects affected / exposed[165]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed[166]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed[167]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infusion related hypersensitivity reaction			
subjects affected / exposed[168]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed[169]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed[170]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed[171]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Female genital tract fistula			
subjects affected / exposed[172]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Intermenstrual bleeding			
subjects affected / exposed[173]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	2
Menstruation irregular			
subjects affected / exposed[174]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed[175]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ovarian mass			
subjects affected / exposed[176]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed[177]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Postmenopausal haemorrhage			
subjects affected / exposed[178]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Scrotal dermatitis			
subjects affected / exposed[179]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed[180]	0 / 18 (0.00%)	0 / 40 (0.00%)	4 / 40 (10.00%)
occurrences (all)	0	0	4
Vaginal haemorrhage			
subjects affected / exposed[181]	0 / 18 (0.00%)	6 / 40 (15.00%)	0 / 40 (0.00%)
occurrences (all)	0	6	0

Vulvovaginal discomfort			
subjects affected / exposed[182]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Vulvovaginal dryness			
subjects affected / exposed[183]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Vulvovaginal inflammation			
subjects affected / exposed[184]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed[185]	0 / 18 (0.00%)	3 / 40 (7.50%)	0 / 40 (0.00%)
occurrences (all)	0	4	0
Chronic obstructive pulmonary disease			
subjects affected / exposed[186]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed[187]	3 / 18 (16.67%)	6 / 40 (15.00%)	6 / 40 (15.00%)
occurrences (all)	3	6	7
Dry throat			
subjects affected / exposed[188]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed[189]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed[190]	1 / 18 (5.56%)	6 / 40 (15.00%)	6 / 40 (15.00%)
occurrences (all)	2	7	6
Dyspnoea exertional			
subjects affected / exposed[191]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed[192]	5 / 18 (27.78%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	6	1	0
Haemoptysis			

subjects affected / exposed[193]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed[194]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed[195]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Laryngeal haemorrhage			
subjects affected / exposed[196]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed[197]	2 / 18 (11.11%)	3 / 40 (7.50%)	2 / 40 (5.00%)
occurrences (all)	2	4	2
Nasal dryness			
subjects affected / exposed[198]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Nasal ulcer			
subjects affected / exposed[199]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal discomfort			
subjects affected / exposed[200]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed[201]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed[202]	0 / 18 (0.00%)	4 / 40 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	5	0
Pleuritic pain			
subjects affected / exposed[203]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed[204]	3 / 18 (16.67%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
Productive cough			

subjects affected / exposed[205]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Pulmonary embolism			
subjects affected / exposed[206]	2 / 18 (11.11%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	2	2	0
Pulmonary haemorrhage			
subjects affected / exposed[207]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pulmonary pain			
subjects affected / exposed[208]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed[209]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed[210]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed[211]	2 / 18 (11.11%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Sinus pain			
subjects affected / exposed[212]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Sleep apnoea syndrome			
subjects affected / exposed[213]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed[214]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Throat irritation			
subjects affected / exposed[215]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Throat tightness			
subjects affected / exposed[216]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough syndrome			

subjects affected / exposed[217]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed[218]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed[219]	2 / 18 (11.11%)	4 / 40 (10.00%)	3 / 40 (7.50%)
occurrences (all)	2	4	3
Confusional state			
subjects affected / exposed[220]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed[221]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed[222]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed[223]	0 / 18 (0.00%)	0 / 40 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Hallucinations, mixed			
subjects affected / exposed[224]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Initial insomnia			
subjects affected / exposed[225]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed[226]	1 / 18 (5.56%)	4 / 40 (10.00%)	1 / 40 (2.50%)
occurrences (all)	1	4	1
Irritability			
subjects affected / exposed[227]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Middle insomnia			
subjects affected / exposed[228]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0

Mood swings			
subjects affected / exposed[229]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Nervousness			
subjects affected / exposed[230]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Nightmare			
subjects affected / exposed[231]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion			
subjects affected / exposed[232]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed[233]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed[234]	3 / 18 (16.67%)	2 / 40 (5.00%)	3 / 40 (7.50%)
occurrences (all)	3	2	4
Amylase			
subjects affected / exposed[235]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed[236]	7 / 18 (38.89%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	14	1	0
Aspartate aminotransferase increased			
subjects affected / exposed[237]	4 / 18 (22.22%)	2 / 40 (5.00%)	3 / 40 (7.50%)
occurrences (all)	4	2	4
Bacterial test positive			
subjects affected / exposed[238]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed[239]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			

subjects affected / exposed[240]	0 / 18 (0.00%)	3 / 40 (7.50%)	2 / 40 (5.00%)
occurrences (all)	0	3	2
Blood bilirubin increased			
subjects affected / exposed[241]	2 / 18 (11.11%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	3	1	0
Blood cholesterol increased			
subjects affected / exposed[242]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed[243]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed[244]	0 / 18 (0.00%)	7 / 40 (17.50%)	1 / 40 (2.50%)
occurrences (all)	0	9	1
Blood fibrinogen increased			
subjects affected / exposed[245]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Blood glucose increased			
subjects affected / exposed[246]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			
subjects affected / exposed[247]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed[248]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed[249]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed[250]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Blood triglycerides increased			

subjects affected / exposed[251]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood uric acid decreased			
subjects affected / exposed[252]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed[253]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Carbohydrate antigen 125 increased			
subjects affected / exposed[254]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Cardiac murmur			
subjects affected / exposed[255]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Eosinophil count increased			
subjects affected / exposed[256]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed[257]	3 / 18 (16.67%)	5 / 40 (12.50%)	1 / 40 (2.50%)
occurrences (all)	4	5	1
General physical condition abnormal			
subjects affected / exposed[258]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			
subjects affected / exposed[259]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed[260]	2 / 18 (11.11%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
International normalised ratio increased			
subjects affected / exposed[261]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Lipase increased			

subjects affected / exposed[262]	9 / 18 (50.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	14	0	0
Lymphocyte count decreased			
subjects affected / exposed[263]	2 / 18 (11.11%)	2 / 40 (5.00%)	2 / 40 (5.00%)
occurrences (all)	3	2	4
Neutrophil count decreased			
subjects affected / exposed[264]	5 / 18 (27.78%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	7	0	1
Platelet count decreased			
subjects affected / exposed[265]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Transaminases increased			
subjects affected / exposed[266]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed[267]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed[268]	0 / 18 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	0	2	2
Weight decreased			
subjects affected / exposed[269]	5 / 18 (27.78%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	5	0	1
Weight increased			
subjects affected / exposed[270]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed[271]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	3	1	1
White blood cells urine positive			
subjects affected / exposed[272]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Troponin I increased			
subjects affected / exposed[273]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural			

complications			
Ankle fracture			
subjects affected / exposed[274]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed[275]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed[276]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed[277]	1 / 18 (5.56%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	1	2	0
Infusion related reaction			
subjects affected / exposed[278]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Muscle strain			
subjects affected / exposed[279]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nail injury			
subjects affected / exposed[280]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed[281]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed[282]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed[283]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed[284]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			

subjects affected / exposed[285]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Stoma site discomfort			
subjects affected / exposed[286]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed[287]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed[288]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed[289]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed[290]	0 / 18 (0.00%)	0 / 40 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[291]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Angina pectoris			
subjects affected / exposed[292]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Atrial fibrillation			
subjects affected / exposed[293]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Atrioventricular block first degree			
subjects affected / exposed[294]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed[295]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed[296]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0

Conduction disorder			
subjects affected / exposed[297]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Myocarditis			
subjects affected / exposed[298]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed[299]	0 / 18 (0.00%)	1 / 40 (2.50%)	2 / 40 (5.00%)
occurrences (all)	0	1	2
Pericardial effusion			
subjects affected / exposed[300]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed[301]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed[302]	2 / 18 (11.11%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	2	1	1
Ventricular tachycardia			
subjects affected / exposed[303]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Amnesia			
subjects affected / exposed[304]	1 / 18 (5.56%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Ataxia			
subjects affected / exposed[305]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Balance disorder			
subjects affected / exposed[306]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Burning sensation			
subjects affected / exposed[307]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Central nervous system necrosis			

subjects affected / exposed[308]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Cerebrospinal fluid leakage			
subjects affected / exposed[309]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed[310]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Disturbance in attention			
subjects affected / exposed[311]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed[312]	2 / 18 (11.11%)	5 / 40 (12.50%)	0 / 40 (0.00%)
occurrences (all)	2	5	0
Dysaesthesia			
subjects affected / exposed[313]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Dysarthria			
subjects affected / exposed[314]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed[315]	3 / 18 (16.67%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	3	2	0
Encephalomalacia			
subjects affected / exposed[316]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed[317]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed[318]	0 / 18 (0.00%)	4 / 40 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	5	0
Hypersomnia			
subjects affected / exposed[319]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed[320]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed[321]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Lhermitte's sign			
subjects affected / exposed[322]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Loss of consciousness			
subjects affected / exposed[323]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed[324]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Metabolic encephalopathy			
subjects affected / exposed[325]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed[326]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed[327]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed[328]	11 / 18 (61.11%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	14	1	1
Paraesthesia			
subjects affected / exposed[329]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Peripheral sensory neuropathy			
subjects affected / exposed[330]	5 / 18 (27.78%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	6	2	0
Presyncope			
subjects affected / exposed[331]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Seizure			

subjects affected / exposed[332]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed[333]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Speech disorder			
subjects affected / exposed[334]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed[335]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed[336]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed[337]	0 / 18 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[338]	2 / 18 (11.11%)	9 / 40 (22.50%)	10 / 40 (25.00%)
occurrences (all)	4	11	10
Iron deficiency anaemia			
subjects affected / exposed[339]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed[340]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed[341]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed[342]	6 / 18 (33.33%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	8	2	0
Thrombocytopenia			
subjects affected / exposed[343]	3 / 18 (16.67%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	3	0	2

Thrombocytosis			
subjects affected / exposed[344]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[345]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed[346]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed[347]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed[348]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hypoacusis			
subjects affected / exposed[349]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed[350]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed[351]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed[352]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed[353]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed[354]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Blepharospasm			

subjects affected / exposed[355]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed[356]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Diplopia			
subjects affected / exposed[357]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed[358]	2 / 18 (11.11%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Eye discharge			
subjects affected / exposed[359]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed[360]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed[361]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed[362]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed[363]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed[364]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed[365]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed[366]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Photophobia			

subjects affected / exposed[367]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed[368]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed[369]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed[370]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed[371]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed[372]	1 / 18 (5.56%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Abdominal distension			
subjects affected / exposed[373]	1 / 18 (5.56%)	3 / 40 (7.50%)	1 / 40 (2.50%)
occurrences (all)	1	5	1
Abdominal hernia			
subjects affected / exposed[374]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed[375]	6 / 18 (33.33%)	5 / 40 (12.50%)	8 / 40 (20.00%)
occurrences (all)	6	5	9
Abdominal pain lower			
subjects affected / exposed[376]	0 / 18 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Abdominal pain upper			
subjects affected / exposed[377]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Abdominal rigidity			
subjects affected / exposed[378]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Anal haemorrhage			
subjects affected / exposed[379]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed[380]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Anorectal discomfort			
subjects affected / exposed[381]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed[382]	0 / 18 (0.00%)	4 / 40 (10.00%)	2 / 40 (5.00%)
occurrences (all)	0	5	2
Autoimmune pancreatitis			
subjects affected / exposed[383]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed[384]	2 / 18 (11.11%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	2	0	1
Constipation			
subjects affected / exposed[385]	3 / 18 (16.67%)	4 / 40 (10.00%)	9 / 40 (22.50%)
occurrences (all)	3	4	9
Defaecation urgency			
subjects affected / exposed[386]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed[387]	6 / 18 (33.33%)	10 / 40 (25.00%)	10 / 40 (25.00%)
occurrences (all)	8	11	12
Dry mouth			
subjects affected / exposed[388]	0 / 18 (0.00%)	1 / 40 (2.50%)	3 / 40 (7.50%)
occurrences (all)	0	1	3
Dyspepsia			
subjects affected / exposed[389]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Dysphagia			
subjects affected / exposed[390]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1

Epigastric discomfort			
subjects affected / exposed[391]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed[392]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed[393]	0 / 18 (0.00%)	3 / 40 (7.50%)	2 / 40 (5.00%)
occurrences (all)	0	3	2
Food poisoning			
subjects affected / exposed[394]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Frequent bowel movements			
subjects affected / exposed[395]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed[396]	2 / 18 (11.11%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	3	0	2
Gastrointestinal haemorrhage			
subjects affected / exposed[397]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed[398]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Glossodynia			
subjects affected / exposed[399]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed[400]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed[401]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed[402]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Hyperaesthesia teeth			
subjects affected / exposed[403]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed[404]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed[405]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed[406]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed[407]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed[408]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed[409]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed[410]	10 / 18 (55.56%)	16 / 40 (40.00%)	13 / 40 (32.50%)
occurrences (all)	10	17	17
Odynophagia			
subjects affected / exposed[411]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed[412]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Paraesthesia oral			
subjects affected / exposed[413]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed[414]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Proctitis			
subjects affected / exposed[415]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rectal discharge			
subjects affected / exposed[416]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed[417]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Rectal spasm			
subjects affected / exposed[418]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed[419]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Retroperitoneal haemorrhage			
subjects affected / exposed[420]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Small intestinal obstruction			
subjects affected / exposed[421]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed[422]	5 / 18 (27.78%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	7	0	1
Toothache			
subjects affected / exposed[423]	0 / 18 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	0	1	1
Umbilical hernia			
subjects affected / exposed[424]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed[425]	3 / 18 (16.67%)	6 / 40 (15.00%)	10 / 40 (25.00%)
occurrences (all)	3	7	10
Hepatobiliary disorders			
Cholelithiasis			

subjects affected / exposed[426]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia			
subjects affected / exposed[427]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed[428]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed[429]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed[430]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed[431]	2 / 18 (11.11%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Blister			
subjects affected / exposed[432]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed[433]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed[434]	8 / 18 (44.44%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	15	2	0
Dermatomyositis			
subjects affected / exposed[435]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Drug eruption			
subjects affected / exposed[436]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed[437]	5 / 18 (27.78%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	5	2	0

Ecchymosis			
subjects affected / exposed[438]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed[439]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed[440]	0 / 18 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Hirsutism			
subjects affected / exposed[441]	2 / 18 (11.11%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Hyperhidrosis			
subjects affected / exposed[442]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Hypertrichosis			
subjects affected / exposed[443]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed[444]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed[445]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed[446]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed[447]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Miliaria			
subjects affected / exposed[448]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed[449]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0

Nail disorder			
subjects affected / exposed[450]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Nail pigmentation			
subjects affected / exposed[451]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed[452]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed[453]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Onychoclasis			
subjects affected / exposed[454]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed[455]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed[456]	3 / 18 (16.67%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	3	1	0
Petechiae			
subjects affected / exposed[457]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed[458]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed[459]	4 / 18 (22.22%)	7 / 40 (17.50%)	3 / 40 (7.50%)
occurrences (all)	8	7	3
Pruritus allergic			
subjects affected / exposed[460]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Psoriasis			

subjects affected / exposed[461]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed[462]	9 / 18 (50.00%)	3 / 40 (7.50%)	3 / 40 (7.50%)
occurrences (all)	14	3	4
Rash macular			
subjects affected / exposed[463]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed[464]	2 / 18 (11.11%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	8	3	0
Rash pruritic			
subjects affected / exposed[465]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rash vesicular			
subjects affected / exposed[466]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed[467]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin discolouration			
subjects affected / exposed[468]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Skin disorder			
subjects affected / exposed[469]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin erosion			
subjects affected / exposed[470]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Skin exfoliation			
subjects affected / exposed[471]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed[472]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Skin hyperpigmentation			

subjects affected / exposed[473]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed[474]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Skin mass			
subjects affected / exposed[475]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Skin reaction			
subjects affected / exposed[476]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed[477]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed[478]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Trichorrhexis			
subjects affected / exposed[479]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed[480]	2 / 18 (11.11%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed[481]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Bladder irritation			
subjects affected / exposed[482]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Bladder pain			
subjects affected / exposed[483]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Chromaturia			
subjects affected / exposed[484]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0

Dysuria			
subjects affected / exposed[485]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed[486]	0 / 18 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Hydronephrosis			
subjects affected / exposed[487]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Hypertonic bladder			
subjects affected / exposed[488]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed[489]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed[490]	0 / 18 (0.00%)	2 / 40 (5.00%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Proteinuria			
subjects affected / exposed[491]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Renal failure			
subjects affected / exposed[492]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Renal infarct			
subjects affected / exposed[493]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Renal tubular necrosis			
subjects affected / exposed[494]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Urinary fistula			
subjects affected / exposed[495]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Urinary incontinence			
subjects affected / exposed[496]	1 / 18 (5.56%)	1 / 40 (2.50%)	3 / 40 (7.50%)
occurrences (all)	1	1	3

Urinary retention			
subjects affected / exposed[497]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Urinary tract obstruction			
subjects affected / exposed[498]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Urinary tract pain			
subjects affected / exposed[499]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed[500]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed[501]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Euthyroid sick syndrome			
subjects affected / exposed[502]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed[503]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Hypothyroidism			
subjects affected / exposed[504]	3 / 18 (16.67%)	4 / 40 (10.00%)	2 / 40 (5.00%)
occurrences (all)	3	4	2
Thyroid mass			
subjects affected / exposed[505]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Thyroiditis			
subjects affected / exposed[506]	2 / 18 (11.11%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[507]	3 / 18 (16.67%)	5 / 40 (12.50%)	4 / 40 (10.00%)
occurrences (all)	4	5	4
Arthritis			

subjects affected / exposed[508]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed[509]	2 / 18 (11.11%)	6 / 40 (15.00%)	5 / 40 (12.50%)
occurrences (all)	2	6	5
Bone pain			
subjects affected / exposed[510]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed[511]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Gouty arthritis			
subjects affected / exposed[512]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed[513]	0 / 18 (0.00%)	2 / 40 (5.00%)	2 / 40 (5.00%)
occurrences (all)	0	2	2
Muscle spasms			
subjects affected / exposed[514]	1 / 18 (5.56%)	0 / 40 (0.00%)	2 / 40 (5.00%)
occurrences (all)	1	0	2
Muscular weakness			
subjects affected / exposed[515]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed[516]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal discomfort			
subjects affected / exposed[517]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed[518]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed[519]	0 / 18 (0.00%)	1 / 40 (2.50%)	4 / 40 (10.00%)
occurrences (all)	0	1	4
Neck mass			

subjects affected / exposed[520]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed[521]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed[522]	0 / 18 (0.00%)	4 / 40 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	4	0
Pain in jaw			
subjects affected / exposed[523]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed[524]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed[525]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome			
subjects affected / exposed[526]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed[527]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed[528]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Bacteraemia			
subjects affected / exposed[529]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Bacteriuria			
subjects affected / exposed[530]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Biliary tract infection			
subjects affected / exposed[531]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Breast abscess			
subjects affected / exposed[532]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed[533]	0 / 18 (0.00%)	0 / 40 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Candida infection			
subjects affected / exposed[534]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed[535]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Clostridium bacteraemia			
subjects affected / exposed[536]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Clostridium difficile infection			
subjects affected / exposed[537]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed[538]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Cystitis			
subjects affected / exposed[539]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Cystitis pseudomonal			
subjects affected / exposed[540]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Device related infection			
subjects affected / exposed[541]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Diverticulitis			
subjects affected / exposed[542]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed[543]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Escherichia sepsis			
subjects affected / exposed[544]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed[545]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed[546]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed[547]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed[548]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Gingivitis			
subjects affected / exposed[549]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed[550]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed[551]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed[552]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed[553]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Keratitis viral			
subjects affected / exposed[554]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Kidney infection			
subjects affected / exposed[555]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0

Lip infection			
subjects affected / exposed[556]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed[557]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed[558]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Mucosal infection			
subjects affected / exposed[559]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Nail infection			
subjects affected / exposed[560]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed[561]	0 / 18 (0.00%)	3 / 40 (7.50%)	0 / 40 (0.00%)
occurrences (all)	0	3	0
Oral candidiasis			
subjects affected / exposed[562]	1 / 18 (5.56%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	1	2	0
Oral fungal infection			
subjects affected / exposed[563]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed[564]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Oral infection			
subjects affected / exposed[565]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed[566]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed[567]	4 / 18 (22.22%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	4	0	0

Penile infection			
subjects affected / exposed[568]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Peritonitis			
subjects affected / exposed[569]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed[570]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Pneumonia aspiration			
subjects affected / exposed[571]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Pyuria			
subjects affected / exposed[572]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Rash pustular			
subjects affected / exposed[573]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed[574]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed[575]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Sepsis			
subjects affected / exposed[576]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed[577]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Staphylococcal infection			
subjects affected / exposed[578]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Staphylococcal skin infection			
subjects affected / exposed[579]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0

Streptococcal infection			
subjects affected / exposed[580]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed[581]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed[582]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed[583]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed[584]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection			
subjects affected / exposed[585]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed[586]	1 / 18 (5.56%)	3 / 40 (7.50%)	7 / 40 (17.50%)
occurrences (all)	1	3	9
Urinary tract infection fungal			
subjects affected / exposed[587]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed[588]	0 / 18 (0.00%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	0	2	1
Metabolism and nutrition disorders			
Adult failure to thrive			
subjects affected / exposed[589]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed[590]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			

subjects affected / exposed[591]	5 / 18 (27.78%)	14 / 40 (35.00%)	5 / 40 (12.50%)
occurrences (all)	6	14	5
Dehydration			
subjects affected / exposed[592]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Electrolyte imbalance			
subjects affected / exposed[593]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Failure to thrive			
subjects affected / exposed[594]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed[595]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Hyperamylasaemia			
subjects affected / exposed[596]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed[597]	0 / 18 (0.00%)	2 / 40 (5.00%)	0 / 40 (0.00%)
occurrences (all)	0	2	0
Hypercholesterolaemia			
subjects affected / exposed[598]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed[599]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed[600]	0 / 18 (0.00%)	3 / 40 (7.50%)	0 / 40 (0.00%)
occurrences (all)	0	3	0
Hyperkalaemia			
subjects affected / exposed[601]	2 / 18 (11.11%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	2	1	0
Hyperlipasaemia			
subjects affected / exposed[602]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			

subjects affected / exposed[603]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
subjects affected / exposed[604]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed[605]	2 / 18 (11.11%)	1 / 40 (2.50%)	2 / 40 (5.00%)
occurrences (all)	2	1	2
Hyperuricaemia			
subjects affected / exposed[606]	0 / 18 (0.00%)	3 / 40 (7.50%)	1 / 40 (2.50%)
occurrences (all)	0	3	1
Hypervolaemia			
subjects affected / exposed[607]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed[608]	1 / 18 (5.56%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	1	0	1
Hypocalcaemia			
subjects affected / exposed[609]	0 / 18 (0.00%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Hypochloraemia			
subjects affected / exposed[610]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed[611]	1 / 18 (5.56%)	1 / 40 (2.50%)	1 / 40 (2.50%)
occurrences (all)	1	1	1
Hypokalaemia			
subjects affected / exposed[612]	2 / 18 (11.11%)	4 / 40 (10.00%)	3 / 40 (7.50%)
occurrences (all)	3	6	3
Hypomagnesaemia			
subjects affected / exposed[613]	4 / 18 (22.22%)	3 / 40 (7.50%)	5 / 40 (12.50%)
occurrences (all)	7	3	7
Hyponatraemia			
subjects affected / exposed[614]	1 / 18 (5.56%)	3 / 40 (7.50%)	4 / 40 (10.00%)
occurrences (all)	3	4	4
Hypophagia			

subjects affected / exposed[615]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed[616]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed[617]	0 / 18 (0.00%)	0 / 40 (0.00%)	1 / 40 (2.50%)
occurrences (all)	0	0	1
Malnutrition			
subjects affected / exposed[618]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed[619]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed[620]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed[621]	1 / 18 (5.56%)	1 / 40 (2.50%)	0 / 40 (0.00%)
occurrences (all)	1	1	0
Vitamin B12 deficiency			
subjects affected / exposed[622]	1 / 18 (5.56%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	1	0	0
Vitamin D deficiency			
subjects affected / exposed[623]	0 / 18 (0.00%)	0 / 40 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Exploration Cohort C1B: Mona 750 mg Q2W + Cetu	Exploration Cohort C2A: Mona 750 mg Q2W + Durva + Cetu	Exploration Cohort C2B: Mona 750 mg Q2W + Cetu
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 41 (100.00%)	44 / 44 (100.00%)	36 / 37 (97.30%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed[111]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Cancer pain			

subjects affected / exposed[112]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Malignant ascites			
subjects affected / exposed[113]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma			
subjects affected / exposed[114]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Tumour associated fever			
subjects affected / exposed[115]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed[116]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed[117]	1 / 41 (2.44%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Embolism			
subjects affected / exposed[118]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed[119]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed[120]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed[121]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed[122]	0 / 41 (0.00%)	1 / 44 (2.27%)	3 / 37 (8.11%)
occurrences (all)	0	2	3
Hypotension			
subjects affected / exposed[123]	0 / 41 (0.00%)	3 / 44 (6.82%)	3 / 37 (8.11%)
occurrences (all)	0	3	3

Jugular vein thrombosis			
subjects affected / exposed[124]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Lymphoedema			
subjects affected / exposed[125]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed[126]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Thrombosis			
subjects affected / exposed[127]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Central venous catheterisation			
subjects affected / exposed[128]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed[129]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed[130]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed[131]	3 / 41 (7.32%)	0 / 44 (0.00%)	4 / 37 (10.81%)
occurrences (all)	4	0	4
Catheter site dermatitis			
subjects affected / exposed[132]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Catheter site erosion			
subjects affected / exposed[133]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed[134]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			

subjects affected / exposed[135]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed[136]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed[137]	3 / 41 (7.32%)	8 / 44 (18.18%)	2 / 37 (5.41%)
occurrences (all)	3	11	2
Complication associated with device			
subjects affected / exposed[138]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed[139]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Device related thrombosis			
subjects affected / exposed[140]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed[141]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed[142]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed[143]	8 / 41 (19.51%)	11 / 44 (25.00%)	6 / 37 (16.22%)
occurrences (all)	9	15	6
Gait disturbance			
subjects affected / exposed[144]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
General physical health deterioration			
subjects affected / exposed[145]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Generalised oedema			
subjects affected / exposed[146]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hernia			

subjects affected / exposed[147]	0 / 41 (0.00%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Hernia pain			
subjects affected / exposed[148]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed[149]	1 / 41 (2.44%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	1	4	1
Injection site discomfort			
subjects affected / exposed[150]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed[151]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed[152]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed[153]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Medical device pain			
subjects affected / exposed[154]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed[155]	1 / 41 (2.44%)	0 / 44 (0.00%)	3 / 37 (8.11%)
occurrences (all)	1	0	3
Non-cardiac chest pain			
subjects affected / exposed[156]	0 / 41 (0.00%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	0	2	2
Oedema			
subjects affected / exposed[157]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed[158]	1 / 41 (2.44%)	5 / 44 (11.36%)	2 / 37 (5.41%)
occurrences (all)	1	5	2
Pain			

subjects affected / exposed[159]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed[160]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed[161]	6 / 41 (14.63%)	15 / 44 (34.09%)	6 / 37 (16.22%)
occurrences (all)	9	18	8
Secretion discharge			
subjects affected / exposed[162]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Temperature intolerance			
subjects affected / exposed[163]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed[164]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed[165]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed[166]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed[167]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infusion related hypersensitivity reaction			
subjects affected / exposed[168]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed[169]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed[170]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed[171]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Female genital tract fistula			
subjects affected / exposed[172]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Intermenstrual bleeding			
subjects affected / exposed[173]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed[174]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed[175]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Ovarian mass			
subjects affected / exposed[176]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed[177]	2 / 41 (4.88%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Postmenopausal haemorrhage			
subjects affected / exposed[178]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Scrotal dermatitis			
subjects affected / exposed[179]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed[180]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed[181]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0

Vulvovaginal discomfort			
subjects affected / exposed[182]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal dryness			
subjects affected / exposed[183]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed[184]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed[185]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Chronic obstructive pulmonary disease			
subjects affected / exposed[186]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed[187]	4 / 41 (9.76%)	2 / 44 (4.55%)	4 / 37 (10.81%)
occurrences (all)	4	2	5
Dry throat			
subjects affected / exposed[188]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed[189]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed[190]	4 / 41 (9.76%)	5 / 44 (11.36%)	3 / 37 (8.11%)
occurrences (all)	4	5	3
Dyspnoea exertional			
subjects affected / exposed[191]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed[192]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			

subjects affected / exposed[193]	2 / 41 (4.88%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Hiccups			
subjects affected / exposed[194]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed[195]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Laryngeal haemorrhage			
subjects affected / exposed[196]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed[197]	0 / 41 (0.00%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Nasal dryness			
subjects affected / exposed[198]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed[199]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal discomfort			
subjects affected / exposed[200]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed[201]	0 / 41 (0.00%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Pleural effusion			
subjects affected / exposed[202]	2 / 41 (4.88%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	2	2	1
Pleuritic pain			
subjects affected / exposed[203]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed[204]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Productive cough			

subjects affected / exposed[205]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Pulmonary embolism			
subjects affected / exposed[206]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pulmonary haemorrhage			
subjects affected / exposed[207]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pulmonary pain			
subjects affected / exposed[208]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed[209]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed[210]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed[211]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Sinus pain			
subjects affected / exposed[212]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed[213]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed[214]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed[215]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Throat tightness			
subjects affected / exposed[216]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			

subjects affected / exposed[217]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed[218]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	4	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed[219]	0 / 41 (0.00%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	0	2	1
Confusional state			
subjects affected / exposed[220]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Delirium			
subjects affected / exposed[221]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed[222]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed[223]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hallucinations, mixed			
subjects affected / exposed[224]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed[225]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed[226]	3 / 41 (7.32%)	5 / 44 (11.36%)	4 / 37 (10.81%)
occurrences (all)	3	5	4
Irritability			
subjects affected / exposed[227]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed[228]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Mood swings			
subjects affected / exposed[229]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nervousness			
subjects affected / exposed[230]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed[231]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device occlusion			
subjects affected / exposed[232]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed[233]	2 / 41 (4.88%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Alanine aminotransferase increased			
subjects affected / exposed[234]	4 / 41 (9.76%)	5 / 44 (11.36%)	4 / 37 (10.81%)
occurrences (all)	4	5	4
Amylase			
subjects affected / exposed[235]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed[236]	1 / 41 (2.44%)	5 / 44 (11.36%)	4 / 37 (10.81%)
occurrences (all)	3	6	4
Aspartate aminotransferase increased			
subjects affected / exposed[237]	8 / 41 (19.51%)	8 / 44 (18.18%)	6 / 37 (16.22%)
occurrences (all)	11	8	10
Bacterial test positive			
subjects affected / exposed[238]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed[239]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			

subjects affected / exposed[240]	4 / 41 (9.76%)	5 / 44 (11.36%)	4 / 37 (10.81%)
occurrences (all)	4	7	4
Blood bilirubin increased			
subjects affected / exposed[241]	4 / 41 (9.76%)	2 / 44 (4.55%)	4 / 37 (10.81%)
occurrences (all)	4	5	5
Blood cholesterol increased			
subjects affected / exposed[242]	2 / 41 (4.88%)	2 / 44 (4.55%)	3 / 37 (8.11%)
occurrences (all)	2	2	4
Blood creatine increased			
subjects affected / exposed[243]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed[244]	0 / 41 (0.00%)	2 / 44 (4.55%)	3 / 37 (8.11%)
occurrences (all)	0	2	4
Blood fibrinogen increased			
subjects affected / exposed[245]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed[246]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed[247]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blood magnesium decreased			
subjects affected / exposed[248]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blood pressure increased			
subjects affected / exposed[249]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed[250]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blood triglycerides increased			

subjects affected / exposed[251]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Blood uric acid decreased			
subjects affected / exposed[252]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed[253]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Carbohydrate antigen 125 increased			
subjects affected / exposed[254]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed[255]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed[256]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed[257]	5 / 41 (12.20%)	3 / 44 (6.82%)	5 / 37 (13.51%)
occurrences (all)	5	3	7
General physical condition abnormal			
subjects affected / exposed[258]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed[259]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed[260]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed[261]	3 / 41 (7.32%)	1 / 44 (2.27%)	2 / 37 (5.41%)
occurrences (all)	3	1	2
Lipase increased			

subjects affected / exposed[262]	3 / 41 (7.32%)	8 / 44 (18.18%)	6 / 37 (16.22%)
occurrences (all)	5	9	14
Lymphocyte count decreased			
subjects affected / exposed[263]	3 / 41 (7.32%)	3 / 44 (6.82%)	5 / 37 (13.51%)
occurrences (all)	3	3	10
Neutrophil count decreased			
subjects affected / exposed[264]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Platelet count decreased			
subjects affected / exposed[265]	1 / 41 (2.44%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	1	2	1
Transaminases increased			
subjects affected / exposed[266]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tri-iodothyronine free decreased			
subjects affected / exposed[267]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Urine leukocyte esterase positive			
subjects affected / exposed[268]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed[269]	2 / 41 (4.88%)	4 / 44 (9.09%)	3 / 37 (8.11%)
occurrences (all)	2	6	3
Weight increased			
subjects affected / exposed[270]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed[271]	0 / 41 (0.00%)	1 / 44 (2.27%)	2 / 37 (5.41%)
occurrences (all)	0	1	4
White blood cells urine positive			
subjects affected / exposed[272]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed[273]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural			

complications			
Ankle fracture			
subjects affected / exposed[274]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed[275]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed[276]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed[277]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed[278]	9 / 41 (21.95%)	9 / 44 (20.45%)	4 / 37 (10.81%)
occurrences (all)	9	12	4
Muscle strain			
subjects affected / exposed[279]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Nail injury			
subjects affected / exposed[280]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Post-traumatic pain			
subjects affected / exposed[281]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Procedural nausea			
subjects affected / exposed[282]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed[283]	0 / 41 (0.00%)	0 / 44 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Skin laceration			
subjects affected / exposed[284]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Spinal fracture			

subjects affected / exposed[285]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Stoma site discomfort			
subjects affected / exposed[286]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Stoma site pain			
subjects affected / exposed[287]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed[288]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Wound dehiscence			
subjects affected / exposed[289]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Wrist fracture			
subjects affected / exposed[290]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed[291]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Angina pectoris			
subjects affected / exposed[292]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Atrial fibrillation			
subjects affected / exposed[293]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block first degree			
subjects affected / exposed[294]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed[295]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cardiomegaly			
subjects affected / exposed[296]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Conduction disorder			
subjects affected / exposed[297]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Myocarditis			
subjects affected / exposed[298]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed[299]	0 / 41 (0.00%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Pericardial effusion			
subjects affected / exposed[300]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed[301]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed[302]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Ventricular tachycardia			
subjects affected / exposed[303]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed[304]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed[305]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed[306]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed[307]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Central nervous system necrosis			

subjects affected / exposed[308]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cerebrospinal fluid leakage			
subjects affected / exposed[309]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed[310]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed[311]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed[312]	2 / 41 (4.88%)	3 / 44 (6.82%)	2 / 37 (5.41%)
occurrences (all)	2	3	2
Dysaesthesia			
subjects affected / exposed[313]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Dysarthria			
subjects affected / exposed[314]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed[315]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Encephalomalacia			
subjects affected / exposed[316]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed[317]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed[318]	17 / 41 (41.46%)	12 / 44 (27.27%)	8 / 37 (21.62%)
occurrences (all)	19	13	9
Hypersomnia			
subjects affected / exposed[319]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed[320]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Lethargy			
subjects affected / exposed[321]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Lhermitte's sign			
subjects affected / exposed[322]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed[323]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed[324]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Metabolic encephalopathy			
subjects affected / exposed[325]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed[326]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed[327]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed[328]	1 / 41 (2.44%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	1	2	1
Paraesthesia			
subjects affected / exposed[329]	0 / 41 (0.00%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Peripheral sensory neuropathy			
subjects affected / exposed[330]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Presyncope			
subjects affected / exposed[331]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Seizure			

subjects affected / exposed[332]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed[333]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Speech disorder			
subjects affected / exposed[334]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed[335]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed[336]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed[337]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed[338]	1 / 41 (2.44%)	4 / 44 (9.09%)	4 / 37 (10.81%)
occurrences (all)	1	4	5
Iron deficiency anaemia			
subjects affected / exposed[339]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed[340]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed[341]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed[342]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed[343]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1

Thrombocytosis			
subjects affected / exposed[344]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed[345]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear disorder			
subjects affected / exposed[346]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed[347]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed[348]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hypoacusis			
subjects affected / exposed[349]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Middle ear effusion			
subjects affected / exposed[350]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Otorrhoea			
subjects affected / exposed[351]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed[352]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed[353]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blepharitis			
subjects affected / exposed[354]	0 / 41 (0.00%)	0 / 44 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Blepharospasm			

subjects affected / exposed[355]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed[356]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Diplopia			
subjects affected / exposed[357]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed[358]	1 / 41 (2.44%)	1 / 44 (2.27%)	2 / 37 (5.41%)
occurrences (all)	1	1	2
Eye discharge			
subjects affected / exposed[359]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed[360]	0 / 41 (0.00%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	0	3	0
Eye pain			
subjects affected / exposed[361]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Eye pruritus			
subjects affected / exposed[362]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eyelids pruritus			
subjects affected / exposed[363]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed[364]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed[365]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed[366]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Photophobia			

subjects affected / exposed[367]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pterygium			
subjects affected / exposed[368]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed[369]	0 / 41 (0.00%)	3 / 44 (6.82%)	0 / 37 (0.00%)
occurrences (all)	0	5	0
Visual impairment			
subjects affected / exposed[370]	0 / 41 (0.00%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Vitreous floaters			
subjects affected / exposed[371]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed[372]	2 / 41 (4.88%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	2	0	1
Abdominal distension			
subjects affected / exposed[373]	1 / 41 (2.44%)	6 / 44 (13.64%)	1 / 37 (2.70%)
occurrences (all)	1	7	1
Abdominal hernia			
subjects affected / exposed[374]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed[375]	7 / 41 (17.07%)	7 / 44 (15.91%)	2 / 37 (5.41%)
occurrences (all)	7	7	2
Abdominal pain lower			
subjects affected / exposed[376]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed[377]	1 / 41 (2.44%)	1 / 44 (2.27%)	3 / 37 (8.11%)
occurrences (all)	1	1	3
Abdominal rigidity			
subjects affected / exposed[378]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Anal haemorrhage			
subjects affected / exposed[379]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed[380]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed[381]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed[382]	1 / 41 (2.44%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	1	1	1
Autoimmune pancreatitis			
subjects affected / exposed[383]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed[384]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed[385]	7 / 41 (17.07%)	10 / 44 (22.73%)	1 / 37 (2.70%)
occurrences (all)	8	12	1
Defaecation urgency			
subjects affected / exposed[386]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed[387]	5 / 41 (12.20%)	9 / 44 (20.45%)	7 / 37 (18.92%)
occurrences (all)	7	12	10
Dry mouth			
subjects affected / exposed[388]	0 / 41 (0.00%)	3 / 44 (6.82%)	0 / 37 (0.00%)
occurrences (all)	0	3	0
Dyspepsia			
subjects affected / exposed[389]	1 / 41 (2.44%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Dysphagia			
subjects affected / exposed[390]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Epigastric discomfort			
subjects affected / exposed[391]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed[392]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed[393]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed[394]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed[395]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed[396]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Gastrointestinal haemorrhage			
subjects affected / exposed[397]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed[398]	1 / 41 (2.44%)	1 / 44 (2.27%)	2 / 37 (5.41%)
occurrences (all)	1	1	2
Glossodynia			
subjects affected / exposed[399]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed[400]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed[401]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed[402]	3 / 41 (7.32%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	3	0	1

Hyperaesthesia teeth			
subjects affected / exposed[403]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed[404]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed[405]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Impaired gastric emptying			
subjects affected / exposed[406]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Lip dry			
subjects affected / exposed[407]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed[408]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed[409]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed[410]	8 / 41 (19.51%)	8 / 44 (18.18%)	7 / 37 (18.92%)
occurrences (all)	9	9	8
Odynophagia			
subjects affected / exposed[411]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed[412]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed[413]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed[414]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Proctitis			
subjects affected / exposed[415]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rectal discharge			
subjects affected / exposed[416]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed[417]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Rectal spasm			
subjects affected / exposed[418]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rectal tenesmus			
subjects affected / exposed[419]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Retroperitoneal haemorrhage			
subjects affected / exposed[420]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Small intestinal obstruction			
subjects affected / exposed[421]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed[422]	1 / 41 (2.44%)	6 / 44 (13.64%)	3 / 37 (8.11%)
occurrences (all)	1	8	3
Toothache			
subjects affected / exposed[423]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed[424]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed[425]	8 / 41 (19.51%)	7 / 44 (15.91%)	1 / 37 (2.70%)
occurrences (all)	8	8	1
Hepatobiliary disorders			
Cholelithiasis			

subjects affected / exposed[426]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed[427]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed[428]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed[429]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed[430]	0 / 41 (0.00%)	0 / 44 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	4
Alopecia			
subjects affected / exposed[431]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blister			
subjects affected / exposed[432]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed[433]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed[434]	24 / 41 (58.54%)	28 / 44 (63.64%)	23 / 37 (62.16%)
occurrences (all)	24	41	25
Dermatomyositis			
subjects affected / exposed[435]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed[436]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed[437]	5 / 41 (12.20%)	3 / 44 (6.82%)	10 / 37 (27.03%)
occurrences (all)	5	3	10

Ecchymosis			
subjects affected / exposed[438]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed[439]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed[440]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hirsutism			
subjects affected / exposed[441]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed[442]	2 / 41 (4.88%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	2	4	0
Hypertrichosis			
subjects affected / exposed[443]	3 / 41 (7.32%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	3	1	0
Ingrowing nail			
subjects affected / exposed[444]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Intertrigo			
subjects affected / exposed[445]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Lichen planus			
subjects affected / exposed[446]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Madarosis			
subjects affected / exposed[447]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed[448]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nail discolouration			
subjects affected / exposed[449]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Nail disorder			
subjects affected / exposed[450]	0 / 41 (0.00%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Nail pigmentation			
subjects affected / exposed[451]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed[452]	0 / 41 (0.00%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Onychalgia			
subjects affected / exposed[453]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Onychoclasis			
subjects affected / exposed[454]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed[455]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed[456]	0 / 41 (0.00%)	3 / 44 (6.82%)	0 / 37 (0.00%)
occurrences (all)	0	3	0
Petechiae			
subjects affected / exposed[457]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed[458]	0 / 41 (0.00%)	3 / 44 (6.82%)	0 / 37 (0.00%)
occurrences (all)	0	4	0
Pruritus			
subjects affected / exposed[459]	8 / 41 (19.51%)	12 / 44 (27.27%)	7 / 37 (18.92%)
occurrences (all)	10	15	11
Pruritus allergic			
subjects affected / exposed[460]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Psoriasis			

subjects affected / exposed[461]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed[462]	8 / 41 (19.51%)	5 / 44 (11.36%)	9 / 37 (24.32%)
occurrences (all)	8	9	9
Rash macular			
subjects affected / exposed[463]	0 / 41 (0.00%)	0 / 44 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	4
Rash maculo-papular			
subjects affected / exposed[464]	5 / 41 (12.20%)	4 / 44 (9.09%)	4 / 37 (10.81%)
occurrences (all)	5	6	4
Rash pruritic			
subjects affected / exposed[465]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Rash vesicular			
subjects affected / exposed[466]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed[467]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Skin discolouration			
subjects affected / exposed[468]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed[469]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Skin erosion			
subjects affected / exposed[470]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed[471]	1 / 41 (2.44%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	1	3	0
Skin fissures			
subjects affected / exposed[472]	2 / 41 (4.88%)	3 / 44 (6.82%)	1 / 37 (2.70%)
occurrences (all)	2	3	1
Skin hyperpigmentation			

subjects affected / exposed[473]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed[474]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed[475]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin reaction			
subjects affected / exposed[476]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin toxicity			
subjects affected / exposed[477]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed[478]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Trichorrhexis			
subjects affected / exposed[479]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed[480]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed[481]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bladder irritation			
subjects affected / exposed[482]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed[483]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed[484]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0

Dysuria			
subjects affected / exposed[485]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed[486]	2 / 41 (4.88%)	3 / 44 (6.82%)	3 / 37 (8.11%)
occurrences (all)	2	3	3
Hydronephrosis			
subjects affected / exposed[487]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hypertonic bladder			
subjects affected / exposed[488]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed[489]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed[490]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed[491]	2 / 41 (4.88%)	2 / 44 (4.55%)	4 / 37 (10.81%)
occurrences (all)	2	2	5
Renal failure			
subjects affected / exposed[492]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Renal infarct			
subjects affected / exposed[493]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Renal tubular necrosis			
subjects affected / exposed[494]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Urinary fistula			
subjects affected / exposed[495]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed[496]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Urinary retention			
subjects affected / exposed[497]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Urinary tract obstruction			
subjects affected / exposed[498]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed[499]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Urine flow decreased			
subjects affected / exposed[500]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed[501]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Euthyroid sick syndrome			
subjects affected / exposed[502]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hyperthyroidism			
subjects affected / exposed[503]	0 / 41 (0.00%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Hypothyroidism			
subjects affected / exposed[504]	1 / 41 (2.44%)	6 / 44 (13.64%)	5 / 37 (13.51%)
occurrences (all)	1	7	7
Thyroid mass			
subjects affected / exposed[505]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Thyroiditis			
subjects affected / exposed[506]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed[507]	4 / 41 (9.76%)	4 / 44 (9.09%)	1 / 37 (2.70%)
occurrences (all)	4	4	1
Arthritis			

subjects affected / exposed[508]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed[509]	5 / 41 (12.20%)	6 / 44 (13.64%)	2 / 37 (5.41%)
occurrences (all)	5	7	2
Bone pain			
subjects affected / exposed[510]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed[511]	1 / 41 (2.44%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Gouty arthritis			
subjects affected / exposed[512]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed[513]	1 / 41 (2.44%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Muscle spasms			
subjects affected / exposed[514]	0 / 41 (0.00%)	2 / 44 (4.55%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Muscular weakness			
subjects affected / exposed[515]	0 / 41 (0.00%)	3 / 44 (6.82%)	2 / 37 (5.41%)
occurrences (all)	0	3	2
Musculoskeletal chest pain			
subjects affected / exposed[516]	0 / 41 (0.00%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Musculoskeletal discomfort			
subjects affected / exposed[517]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed[518]	0 / 41 (0.00%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed[519]	0 / 41 (0.00%)	9 / 44 (20.45%)	1 / 37 (2.70%)
occurrences (all)	0	10	1
Neck mass			

subjects affected / exposed[520]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed[521]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed[522]	2 / 41 (4.88%)	3 / 44 (6.82%)	0 / 37 (0.00%)
occurrences (all)	2	3	0
Pain in jaw			
subjects affected / exposed[523]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed[524]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed[525]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome			
subjects affected / exposed[526]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed[527]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Abscess			
subjects affected / exposed[528]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Bacteraemia			
subjects affected / exposed[529]	1 / 41 (2.44%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Bacteriuria			
subjects affected / exposed[530]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Biliary tract infection			
subjects affected / exposed[531]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1

Breast abscess			
subjects affected / exposed[532]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed[533]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed[534]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed[535]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Clostridium bacteraemia			
subjects affected / exposed[536]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed[537]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed[538]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Cystitis			
subjects affected / exposed[539]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cystitis pseudomonal			
subjects affected / exposed[540]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed[541]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Diverticulitis			
subjects affected / exposed[542]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Enterocolitis infectious			
subjects affected / exposed[543]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Escherichia sepsis			
subjects affected / exposed[544]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed[545]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed[546]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed[547]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed[548]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed[549]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed[550]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed[551]	0 / 41 (0.00%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	0	2	1
Infection			
subjects affected / exposed[552]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed[553]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Keratitis viral			
subjects affected / exposed[554]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Kidney infection			
subjects affected / exposed[555]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Lip infection			
subjects affected / exposed[556]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed[557]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Medical device site infection			
subjects affected / exposed[558]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed[559]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed[560]	0 / 41 (0.00%)	1 / 44 (2.27%)	2 / 37 (5.41%)
occurrences (all)	0	1	2
Nasopharyngitis			
subjects affected / exposed[561]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed[562]	1 / 41 (2.44%)	1 / 44 (2.27%)	1 / 37 (2.70%)
occurrences (all)	1	1	1
Oral fungal infection			
subjects affected / exposed[563]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed[564]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oral infection			
subjects affected / exposed[565]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed[566]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed[567]	4 / 41 (9.76%)	4 / 44 (9.09%)	6 / 37 (16.22%)
occurrences (all)	4	4	6

Penile infection			
subjects affected / exposed[568]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Peritonitis			
subjects affected / exposed[569]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed[570]	0 / 41 (0.00%)	0 / 44 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Pneumonia aspiration			
subjects affected / exposed[571]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed[572]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed[573]	0 / 41 (0.00%)	4 / 44 (9.09%)	0 / 37 (0.00%)
occurrences (all)	0	4	0
Respiratory tract infection			
subjects affected / exposed[574]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed[575]	1 / 41 (2.44%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Sepsis			
subjects affected / exposed[576]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed[577]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed[578]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed[579]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Streptococcal infection			
subjects affected / exposed[580]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Tinea pedis			
subjects affected / exposed[581]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed[582]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed[583]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed[584]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed[585]	0 / 41 (0.00%)	2 / 44 (4.55%)	2 / 37 (5.41%)
occurrences (all)	0	2	2
Urinary tract infection			
subjects affected / exposed[586]	4 / 41 (9.76%)	3 / 44 (6.82%)	1 / 37 (2.70%)
occurrences (all)	4	3	1
Urinary tract infection fungal			
subjects affected / exposed[587]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed[588]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Adult failure to thrive			
subjects affected / exposed[589]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cachexia			
subjects affected / exposed[590]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			

subjects affected / exposed[591]	5 / 41 (12.20%)	9 / 44 (20.45%)	5 / 37 (13.51%)
occurrences (all)	6	9	6
Dehydration			
subjects affected / exposed[592]	2 / 41 (4.88%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Electrolyte imbalance			
subjects affected / exposed[593]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed[594]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed[595]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperamylasaemia			
subjects affected / exposed[596]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed[597]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed[598]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypercreatininaemia			
subjects affected / exposed[599]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed[600]	0 / 41 (0.00%)	1 / 44 (2.27%)	2 / 37 (5.41%)
occurrences (all)	0	1	2
Hyperkalaemia			
subjects affected / exposed[601]	1 / 41 (2.44%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	1	4	1
Hyperlipasaemia			
subjects affected / exposed[602]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			

subjects affected / exposed[603]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed[604]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed[605]	3 / 41 (7.32%)	1 / 44 (2.27%)	3 / 37 (8.11%)
occurrences (all)	3	2	6
Hyperuricaemia			
subjects affected / exposed[606]	1 / 41 (2.44%)	2 / 44 (4.55%)	1 / 37 (2.70%)
occurrences (all)	1	3	1
Hypervolaemia			
subjects affected / exposed[607]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed[608]	4 / 41 (9.76%)	3 / 44 (6.82%)	1 / 37 (2.70%)
occurrences (all)	4	4	2
Hypocalcaemia			
subjects affected / exposed[609]	0 / 41 (0.00%)	6 / 44 (13.64%)	3 / 37 (8.11%)
occurrences (all)	0	8	4
Hypochloraemia			
subjects affected / exposed[610]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed[611]	1 / 41 (2.44%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed[612]	2 / 41 (4.88%)	5 / 44 (11.36%)	5 / 37 (13.51%)
occurrences (all)	2	7	6
Hypomagnesaemia			
subjects affected / exposed[613]	8 / 41 (19.51%)	9 / 44 (20.45%)	10 / 37 (27.03%)
occurrences (all)	8	13	21
Hyponatraemia			
subjects affected / exposed[614]	6 / 41 (14.63%)	5 / 44 (11.36%)	4 / 37 (10.81%)
occurrences (all)	8	5	5
Hypophagia			

subjects affected / exposed[615]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed[616]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed[617]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed[618]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Metabolic acidosis			
subjects affected / exposed[619]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed[620]	0 / 41 (0.00%)	1 / 44 (2.27%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Type 2 diabetes mellitus			
subjects affected / exposed[621]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed[622]	0 / 41 (0.00%)	0 / 44 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed[623]	0 / 41 (0.00%)	0 / 44 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1

Notes:

[111] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: In AE section death data was analysed as per ITT population and AE/SAE data was analysed as per As-treated population. Hence, for Cohort C1A "Number of subjects exposed" for each adverse event is less than the "Total number of subjects exposed".

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[621] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 January 2016	The dose limiting toxicity (DLT) definition was modified to include any Grade 3/4 laboratory abnormality requiring hospitalization for the management of toxicities and any delays in monalizumab dosing due to a treatment-related AE. Exclusions were added to the DLT definition: Grade 3 nausea/vomiting or Grade 4 vomiting in the absence of maximal medical therapy that resolves in 3 days, and Grade 3 hypertension that can be controlled with medical therapy. Inclusion criteria were updated to require: Advanced ovarian cancer participants to have previously received and progressed while on or within 6 months of completing a platinum-based regimen, and metastatic castration-resistant prostate cancer participants to have progressed from either abiraterone or enzalutamide. Appendix 2, Management of Study Medication Related Toxicities was revised to require permanent discontinuation of study drugs if immune-mediated neurotoxicities were not resolved to =< Grade 1 within 14 days.
10 January 2018	Revised the study design (Section 3) to include Part 3 (dose exploration part of the study), cohorts A and B. The primary hypothesis, study objectives and endpoints, rationale, inclusion and exclusion criteria, and sample size were revised to support the addition of Part 3 of the study. Assessment of tumor response, in the Exploratory Analysis of Tumor Response section, was changed from irRECIST to iRECIST.
31 August 2018	New exploration cohorts were added to Part 3 to evaluate monalizumab with cetuximab in participants with 3L MSS-CRC that is RAS/BRAF wild type (Part 3, cohort C2B) as well as RAS mutant (Part 3, cohort C1B). Study treatments administered were revised to include durvalumab in combination with monalizumab plus cetuximab in participants with 3L MSS-CRC that is RAS mutant (Part 3, cohort C1A) as well as RAS/BRAF wild type (Part 3, cohort C2A). Specified maximum time of treatment in study was 3 years.
22 February 2019	Secondary objectives and associated endpoints revised to include EGFR expression in pretreatment tumor biopsies. In exploratory objectives, endpoints specified mass spectrometry, DNA/RNA/miRNA assessments. Potential biomarkers were updated to include epigenetic and metabolic assessments on blood and tumors as well as microbiome assessments on baseline stool samples. Added new presentation of monalizumab 375 mg/vial (20 mL vial). Revised prior therapy inclusion criteria for Part 3 C cohorts. Updated the process for identifying and reporting potential Hy's Law and Hy's Law cases.
06 December 2019	Information on management of study medication-related toxicities was moved to a standalone document and reference made to Section 3.1.3 of the CSP for details. A new section to Study Methods and Schedules of Procedures was added to allow re-treatment following relapse. Participants who progressed during the first 52 weeks after the last dose of study treatment were eligible for re-treatment with the protocol-defined experimental medicines. The investigator could consider standard-of-care chemotherapy backbone with the experimental agent(s) as appropriate for the participant at time of re-treatment.
31 May 2021	Added measures to implement if a participant was not able to visit a study site (Section 3.3 and Section 10.6). Details on the presentation of monalizumab according to vial size were updated. The link to the Toxicity Management Guidance portal was removed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported