# **Clinical trial results:**

An Open-Label, Multicenter, Dose Escalation and Expansion Phase Ib Study to Evaluate the Safety, Pharmacokinetics, and Therapeutic Activity of RO6958688 in Combination with Atezolizumab in Patients with Locally Advanced and/or Metastatic CEA-Positive Solid Tumors

## Summary

EudraCT number	2015-003771-30	
Trial protocol		
Global end of trial date	15 January 2020	
Results information		
Result version number	v1 (current)	
This version publication date		

#### **Trial information**

Trial identification	
Sponsor protocol code	WP29945
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02650713
WHO universal trial number (UTN)	-
N. I	

Notes:

#### Sponsors

Sponsor organisation name	Hoffmann-La Roche
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, 4070
Public contact	F. Hoffmann-La Roche AG, Hoffmann-La Roche, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, Hoffmann-La Roche, +41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Notes:	

#### **Results analysis stage**

Analysis stage

Final

Date of interim/final analysis	15 January 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 January 2020
Was the trial ended prematurely?	No

Notes:

#### General information about the trial

Main objective of the trial:

To evaluate the safety, pharmacokinetics, and therapeutic activity of RO6958688 in combination with atezolizumab in patients with CEA-positive solid tumors, and to establish the appropriate dose and schedule of the combination treatment.

Protection of trial subjects:

All participants were required to sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment07 January 2016Long term follow-up plannedNoIndependent data monitoring committee<br/>(IDMC) involvement?No

Notes:

#### **Population of trial subjects**

Subjects enrolled per country	
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	Denmark: 6
Country: Number of subjects enrolled	Spain: 122
Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Netherlands: 8
Country: Number of subjects enrolled	United States: 69
Worldwide total number of subjects	228
EEA total number of subjects	157
·	157

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)	169
From 65 to 84 years	59
85 years and over	0

# Subject disposition

#### Recruitment

Recruitment details: -

#### **Pre-assignment**

Screening details:

Locally advanced and/or metastatic CEA-positive solid tumors in participants who progressed on a standard therapy, were intolerant to standard of care, and/or were non-amenable to standard of care. Participants must also have had measurable disease according to RECIST v1.1.

#### Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg

#### Arm description:

Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received escalating doses starting from 5 mg up to 80 mg of RO6958688 on Days 1, 8, and 15 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg
-----------	--

Arm description:

Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 100 mg of RO6958 with a fixed dose of atezolizumab.	688 on Days 1, 8, and 15 of each 21-day cycle, in combination
Arm title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Arm description:	
Participants received 160 mg of IV RO69 combination with 1200 mg of IV atezoliz	58688 QW on Days 1, 8, and 15 of each 21-day cycle in umab Q3W.
Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 1200 mg of atezoli	zumab Q3W in combination with cibisatamab.
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 160 mg of RO6958 with a fixed dose of atezolizumab.	688 on Days 1, 8, and 15 of each 21-day cycle, in combination
Arm title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Arm description:	
Participants received 300 mg of IV RO69 combination with 1200 mg of IV atezoliz	58688 QW on Days 1, 8, and 15 of each 21-day cycle in umab Q3W.
Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 1200 mg of atezoli	zumab Q3W in combination with cibisatamab.
Investigational medicinal product name	RO6958688

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

Dosage and administration details:

Participants received 300 mg of RO6958688 on Days 1, 8, and 15 of each 21-day cycle, in combination with a fixed dose of atezolizumab.

Arm title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg

Arm description:

Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.

Arm type

Experimental

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 1200 mg of atezoliz	zumab Q3W in combination with cibisatamab.
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 100 mg of RO6958 dose of atezolizumab.	688 on Day 1 of each 21-day cycle, in combination with a fixed
Arm title	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Arm description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. atezolizumab Q3W.
Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received increasing doses of 21-day cycle, in combination with a fixed	RO6958688 up to 1200 mg, then 1200 mg on Day 1 of each I dose of atezolizumab.
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 1200 mg of atezoliz	zumab Q3W in combination with cibisatamab.
Arm title	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg
Arm description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 150 mg, then 150 mg Q3W. atezolizumab Q3W.
Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received increasing doses of RO6958688 up to 150 mg, then 150 mg on Day 1 of each 21-	
day cycle, in combination with a fixed do	
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	

Other name

Pharmaceutical forms

Solution for infusion

Routes of administration	Intravenous use

Dosage and administration details:

Arm title

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

	mg
Arm description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	

RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200

Other nameCibisatamabPharmaceutical formsSolution for infusionRoutes of administrationIntravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Duct

Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21day cycle, in combination with a fixed dose of atezolizumab.

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

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Breast

Arm title

Arm description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

rancielpantes also received 1200 mg of 10	
Arm type	Experimental

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 1200 mg of atezoliz	zumab Q3W in combination with cibisatamab.
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
5	RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-
day cycle, in combination with a fixed do	
Arm title	Lung
Arm description:	
•	IV RO6958688 QW up to 600 mg, then 600 mg Q3W.
Participants also received 1200 mg of IV	
Arm type	Experimental
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
-	RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21- ose of atezolizumab.
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
-	zumab Q3W in combination with cibisatamab.
Arm title	Pancreatic
Arm description:	
	IV RO6958688 QW up to 600 mg, then 600 mg Q3W.
THE PROPERTY AND A DEC RECOVERED THE ME AT IV	
Participants also received 1200 mg of IV	-
Arm type	Experimental
Arm type Investigational medicinal product name	-
Arm type Investigational medicinal product name Investigational medicinal product code	Experimental RO6958688
Arm type Investigational medicinal product name Investigational medicinal product code Other name	Experimental RO6958688 Cibisatamab
Arm type Investigational medicinal product name Investigational medicinal product code Other name Pharmaceutical forms	Experimental RO6958688 Cibisatamab Solution for infusion
Arm type Investigational medicinal product name Investigational medicinal product code Other name Pharmaceutical forms Routes of administration	Experimental RO6958688 Cibisatamab
Arm type Investigational medicinal product name Investigational medicinal product code Other name Pharmaceutical forms Routes of administration Dosage and administration details:	Experimental RO6958688 Cibisatamab Solution for infusion Intravenous use
Arm type Investigational medicinal product name Investigational medicinal product code Other name Pharmaceutical forms Routes of administration Dosage and administration details:	Experimental RO6958688 Cibisatamab Solution for infusion Intravenous use RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-
Arm typeInvestigational medicinal product nameInvestigational medicinal product codeOther namePharmaceutical formsRoutes of administrationDosage and administration details:Participants received increasing doses of day cycle, in combination with a fixed do	Experimental RO6958688 Cibisatamab Solution for infusion Intravenous use RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21-
Arm typeInvestigational medicinal product nameInvestigational medicinal product codeOther namePharmaceutical formsRoutes of administrationDosage and administration details:Participants received increasing doses of day cycle, in combination with a fixed do	Experimental RO6958688 Cibisatamab Solution for infusion Intravenous use RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21- use of atezolizumab.
Arm typeInvestigational medicinal product nameInvestigational medicinal product codeOther namePharmaceutical formsRoutes of administrationDosage and administration details:Participants received increasing doses of day cycle, in combination with a fixed doInvestigational medicinal product name	Experimental RO6958688 Cibisatamab Solution for infusion Intravenous use RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21- use of atezolizumab.
Arm typeInvestigational medicinal product nameInvestigational medicinal product codeOther namePharmaceutical formsRoutes of administrationDosage and administration details:Participants received increasing doses of day cycle, in combination with a fixed do Investigational medicinal product nameInvestigational medicinal product code	Experimental RO6958688 Cibisatamab Solution for infusion Intravenous use RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21- use of atezolizumab.

Routes of administration

Intravenous use

Dosage and administration details:

Participants received 1200 mg of atezolizumab Q3W in combination with cibisatamab.

Arm title	Gastric
Arm description:	·
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Participants received 1200 mg of atezoliz	zumab Q3W in combination with cibisatamab.
Investigational medicinal product name	RO6958688
Investigational medicinal product code	
Other name	Cibisatamab
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received increasing doses of RO6958688 up to 600 mg, then 600 mg on Day 1 of each 21day cycle, in combination with a fixed dose of atezolizumab.

Number of subjects in period 1	RO6958688 MAD 5- 80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Started	17	24	39
Completed	5	4	10
Not completed	12	20	29
Study Terminated by Sponsor	-	1	-
Disease Progression	1	1	2
Death	10	13	16
Physician decision	-	-	1
Symptomatic Deterioration	-	-	2
Not specified	1	1	3
Consent withdrawn by subject	-	4	5
Lost to follow-up	-	-	-

Number of subjects in period 1			
Started	1	20	17
Completed	1	4	4

Clinical trial results 2015-003771-30 version 1

Not completed	0	16	13
Study Terminated by Sponsor	-	-	-
Disease Progression	-	3	1
Death	-	10	12
Physician decision	-	-	-
Symptomatic Deterioration	-	1	-
Not specified	-	1	-
Consent withdrawn by subject	-	-	-
Lost to follow-up	_	1	-

C1 to 150 mg CRC +	C2 to 600 mg CRC +	
39	35	2
16	10	0
23	25	2
-	1	-
3	1	-
15	18	2
-	1	-
-	-	-
2	-	-
2	2	-
1	2	-
	C1 to 150 mg CRC + Atezolizumab 1200 mg 39 16 23 - 3 15 - - - 2	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

Number of subjects in period 1	Breast	Lung	Pancreatic
Started	2	3	17
Completed	2	0	1
Not completed	0	3	16
Study Terminated by Sponsor	-	-	-
Disease Progression	-	1	2
Death	-	2	13
Physician decision	-	-	-
Symptomatic Deterioration	-	-	-
Not specified	-	-	1
Consent withdrawn by subject	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Gastric
Started	12
Completed	4
Not completed	8

Study Terminated by Sponsor	-
Disease Progression	2
Death	4
Physician decision	-
Symptomatic Deterioration	1
Not specified	-
Consent withdrawn by subject	1
Lost to follow-up	-

Reporting groups	
Reporting group title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
	06958688 weekly (QW) on Days 1, 8, and 15 of each 21-day g up to 80 mg, in combination with a fixed dose (1200 mg) of IV
Reporting group title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO69 combination with 1200 mg of IV atezolize	58688 QW on Days 1, 8, and 15 of each 21-day cycle in umab Q3W.
Reporting group title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
combination with 1200 mg of IV atezoliz	
Reporting group title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
combination with 1200 mg of IV atezoliz	
Reporting group title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO69 1200 mg of IV atezolizumab Q3W.	58688 Q3W on Day 1 of each 21-day cycle, in combination with
Reporting group title	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. atezolizumab Q3W.
Reporting group title	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 150 mg, then 150 mg Q3W. atezolizumab Q3W.
Reporting group title	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Bile Duct
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Breast
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Lung
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Pancreatic
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Gastric

#### Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group values	RO6958688 MAD 5-	RO6958688 MAD	RO6958688 MAD
	80 mg QW CRC +	100 mg QW CRC +	160 mg QW CRC +
	Atezolizumab 1200 mg	Atezolizumab 1200 mg	Atezolizumab 1200 mg
Number of subjects	17	24	39
Age categorical	17	2.1	
Units: Subjects			
Adults (18-64 years)	15	18	28
From 65-84 years	2	6	11
i	2	0	11
Age Continuous			
9999 = not evaluable for one subject			
Units: years			
arithmetic mean	54.9	58.2	56.6
standard deviation	± 9.6	± 11.5	± 11.7
Sex: Female, Male			
Units: Participants			
Female	5	3	22
Male	12	21	17
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	2
White	17	24	36
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	3	5	3
Not Hispanic or Latino	14	19	36
Unknown or Not Reported	0	0	0
Reporting group values	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Number of subjects	1	20	17
Age categorical			
Units: Subjects			
Adults (18-64 years)	0	16	11
From 65-84 years	1	4	6
Age Continuous			-
9999 = not evaluable for one subject		1	1
Units: years			
arithmetic mean	75.0	56.5	59.4
standard deviation	± 9999	± 12.6	± 11.2
Statiualu ueviation		- 12.0	L <u> </u>

	1		
Sex: Female, Male			
Units: Participants			
Female	0	7	7
Male	1	13	10
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	1	19	17
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)	-	_	-
Units: Subjects			
Hispanic or Latino	0	5	0
Not Hispanic or Latino	1	14	17
Unknown or Not Reported	0	1	0
		1	U
Reporting group values		RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg	Bile Duct
Number of subjects	39	35	2
Age categorical			
Units: Subjects			
Adults (18-64 years)	29	28	0
From 65-84 years	10	7	2
Age Continuous			
9999 = not evaluable for one subject			
Units: years			
arithmetic mean	55.7	51.2	68.0
standard deviation	± 11.0	± 13.3	± 0.0
Sex: Female, Male	- 11.0	- 15.5	- 0.0
Units: Participants			
Female	14	21	1
Male	25	14	1
	25	17	Ŧ
Race (NIH/OMB)			
Units: Subjects		0	
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	1	0	0
White	38	32	2
More than one race	0	0	0
Unknown or Not Reported	0	2	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	5	1
Not Hispanic or Latino	37	29	1
Unknown or Not Reported	0	1	0

Reporting group values	Breast	Lung	Pancreatic
Number of subjects	2	3	17
Age categorical			
Units: Subjects			
Adults (18-64 years)	2	2	12
From 65-84 years	0	1	5
Age Continuous			
9999 = not evaluable for one subject			
Units: years			
arithmetic mean	49.0	62.7	59.5
standard deviation	± 4.2	± 10.5	± 10.1
Sex: Female, Male			
Units: Participants			
Female	2	1	10
Male	0	2	7
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific	0	0	0
Islander			
Black or African American	0	0	0
White	2	3	15
More than one race	0	0	0
Unknown or Not Reported	0	0	2
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	3
Not Hispanic or Latino	2	2	11
Unknown or Not Reported	0	0	3
	Costria	Tatal	1
Reporting group values	Gastric	Total	
Number of subjects	12	228	
Age categorical			
Units: Subjects			
Adults (18-64 years)	8	169	
From 65-84 years	4	59	
Age Continuous			
9999 = not evaluable for one subject			
Units: years			
arithmetic mean	59.6		
standard deviation	± 13.5	-	
Sex: Female, Male			
Units: Participants			
Female	3	96	
Male	9	132	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	2	

Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	0	3	
White	12	218	
More than one race	0	0	
Unknown or Not Reported	0	4	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	5	33	
Not Hispanic or Latino	6	189	
Unknown or Not Reported	1	6	

End points reporting groups	
Reporting group title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
	06958688 weekly (QW) on Days 1, 8, and 15 of each 21-day g up to 80 mg, in combination with a fixed dose (1200 mg) of IV
Reporting group title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO69 combination with 1200 mg of IV atezoliz	58688 QW on Days 1, 8, and 15 of each 21-day cycle in umab Q3W.
Reporting group title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 160 mg of IV RO69 combination with 1200 mg of IV atezoliz	58688 QW on Days 1, 8, and 15 of each 21-day cycle in umab Q3W.
Reporting group title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 300 mg of IV RO69 combination with 1200 mg of IV atezoliz	58688 QW on Days 1, 8, and 15 of each 21-day cycle in umab Q3W.
Reporting group title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received 100 mg of IV RO69 1200 mg of IV atezolizumab Q3W.	58688 Q3W on Day 1 of each 21-day cycle, in combination with
Reporting group title	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. atezolizumab Q3W.
Reporting group title	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 150 mg, then 150 mg Q3W. atezolizumab Q3W.
Reporting group title	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Bile Duct
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Breast
Reporting group description:	
	IV RO6958688 QW up to 600 mg, then 600 mg Q3W.
Participants also received 1200 mg of IV	
Reporting group title	Lung
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Pancreatic
Reporting group description:	
Participants received increasing doses of Participants also received 1200 mg of IV	IV RO6958688 QW up to 600 mg, then 600 mg Q3W. atezolizumab Q3W.
Reporting group title	Gastric

Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Participants also received 1200 mg of IV	/ atezolizumab Q3W.
Subject analysis set title	All Participants
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants received up to 1200 mg of 2	IV RO6958688 in combination with 1200 mg of atezolizumab.
Subject analysis set title	All MAD CRC 100-160 mg QW + Q3W
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants with co Q3W in combination with 1200 mg of at	lorectal cancer (CRC) that received RO6958688 either QW or ezolizumab.
Subject analysis set title	ADA-Negative Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included all participants treat with 1200 mg of atezolizumab Q3W that	ted with an initial RO6958688 dose of > 20 mg in combination t were ADA-negative at baseline.
Subject analysis set title	40 mg-QW Cohort
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants that red	ceived 40 mg of IV RO6958688 weekly.
Subject analysis set title	80 mg-QW Cohort
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants that red	ceived 80 mg of IV RO6958688 weekly.
Subject analysis set title	100 mg-QW Cohort
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants that red	ceived 100 mg of IV RO6958688 weekly.
Subject analysis set title	160 mg-QW Cohort
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants that rec	ceived 160 mg of IV RO6958688 weekly.
Subject analysis set title	300 mg-QW Cohort
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants that rec	ceived 300 mg of IV RO6958688 weekly.
Subject analysis set title	100 mg-Q3W Cohort
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants that rec	ceived 100 mg of IV RO6958688 Q3W.
Subject analysis set title	Atezolizumab PK Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
This group included participants that rea quantifiable concentration.	ceived at least one dose of atezolizumab and had at least one

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

End point title

Number of Participants with Adverse Events (AEs)<sup>[1]</sup>

End point description:

An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical

product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events.

End point type	Primary
End point timeframe:	

Baseline up to 60 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this phase I study.

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants	17	24	39	1

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	150 mg CRC +	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants	20	17	39	35

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants	2	2	3	17

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12		
Units: Percentage of Participants	12		

#### Statistical analyses

No statistical analyses for this end point

Clinical trial results 2015-003771-30 version 1

## Primary: Percentage of Participants with Dose-Limiting Toxicities (DLTs)

End point title

Percentage of Participants with Dose-Limiting Toxicities (DLTs)

End point description:

DLTs are side effects of drugs or other treatment serious enough to prevent an increase in dosage or level of treatment.

End point type	Primary
End point timeframe:	
Day 1 up to Day 21	

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: No statistical analyses were planned for this phase I study.

End point values	All Participants		
Subject group type	Subject analysis set		
Number of subjects analysed	228		
Units: Percentage of Participants			
number (not applicable)	6.6		

#### **Statistical analyses**

No statistical analyses for this end point

End point title	rated Dose (MTD) of RO6958688 Maximum-Tolerated Dose (MTD) of RO6958688 <sup>[3]</sup>
End point description:	
	of a drug or treatment that does not cause unacceptable side effects
End point type	Primary
End point timeframe:	· · ·
Day 1 up to Day 21, or Day 1	up to Day 7 after each dose escalation for step-up cohorts
Notos	

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this phase I study.

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17 <sup>[4]</sup>	24 <sup>[5]</sup>	<b>39</b> <sup>[6]</sup>	1 <sup>[7]</sup>
Units: Milligrams (mg)	9999	9999	9999	9999

Notes:

[4] - 9999 = MTD not reached

[5] - 9999 = MTD not reached

- [6] 9999 = MTD not reached
- [7] 9999 = MTD not reached

	RO6958688	RO6958688	RO6958688	RO6958688
	MAD 100 mg	Step Up B1 to	Step Up C1 to	Step Up C2 to
End point values	Q3W CRC +	1200 mg CRC	150 mg CRC +	600 mg CRC +
	Atezolizumab	+ Atezolizumab	Atezolizumab	Atezolizumab
		•		

	1200 mg	1200 mg	1200 mg	1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20 <sup>[8]</sup>	17 <sup>[9]</sup>	<b>39</b> <sup>[10]</sup>	35 <sup>[11]</sup>
Units: Milligrams (mg)	9999	9999	9999	9999

Notes:

[8] - 9999 = MTD not reached

[9] - 9999 = MTD not reached

[10] - 9999 = MTD not reached

[11] - 9999 = MTD not reached

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 <sup>[12]</sup>	2 <sup>[13]</sup>	3 <sup>[14]</sup>	17 <sup>[15]</sup>
Units: Milligrams (mg)	9999	9999	9999	9999

Notes:

[12] - 9999 = MTD not reached

[13] - 9999 = MTD not reached

[14] - 9999 = MTD not reached

[15] - 9999 = MTD not reached

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12 <sup>[16]</sup>		
Units: Milligrams (mg)	9999		

Notes:

[16] - 9999 = MTD not reached

#### **Statistical analyses**

No statistical analyses for this end point

## Primary: Recommended Phase II Dose (RP2D) of RO6958688

End point title	Recommended Phase II Dose (RP2D) of RO6958688 <sup>[17][18]</sup>
End point description:	

End point type

Primary

End point timeframe:

Day 1 up to 60 months

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analyses were planned for this phase I study.

[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: This end point was specific to the groups reported.

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg		
Subject group type	Reporting group		
Number of subjects analysed	20		
Units: Milligrams (mg)	100		

No statistical analyses for this end point

# Secondary: Pharmacokinetic (PK): Area Under the Concentration-Time Curve (AUC) of RO6958688

End point title Pharmacokinetic (PK): Area Under the Concentration-Time Curve (AUC) of RO6958688
---

End point description:

End point type	Secondary	
End point timeframe:		
Baseline up to 60 months		

End point values	40 mg-QW Cohort	80 mg-QW Cohort	100 mg-QW Cohort	160 mg-QW Cohort
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	117 <sup>[19]</sup>	<b>5</b> <sup>[20]</sup>	26 <sup>[21]</sup>	42 <sup>[22]</sup>
Units: (ug x h)/mL				
median (full range (min-max))	455 (183 to 797)	701 (396 to 751)	771 (395 to 1616)	1361 (521 to 2523)

Notes:

[19] - Range values are the 5th (min) and 95th (max) percentiles.

[20] - Range values are the 5th (min) and 95th (max) percentiles.

[21] - Range values are the 5th (min) and 95th (max) percentiles.

[22] - Range values are the 5th (min) and 95th (max) percentiles.

End point values	300 mg-QW Cohort	100 mg-Q3W Cohort	
Subject group type	Subject analysis set	Subject analysis set	
Number of subjects analysed	<b>3</b> <sup>[23]</sup>	20 <sup>[24]</sup>	
Units: (ug x h)/mL			
median (full range (min-max))	2378 (1999 to 3643)	756 (266 to 2398)	

Notes:

[23] - Range values are the 5th (min) and 95th (max) percentiles.

[24] - Range values are the 5th (min) and 95th (max) percentiles.

#### **Statistical analyses**

No statistical analyses for this end point

#### Secondary: PK: Volume of Distribution at Steady State (Vss) of RO6958688

End point title	PK: Volume of Distribution at Steady State (Vss) of RO6958688
End point description:	

End point type	Secondary
End point timeframe:	
Baseline up to 60 months	

End point values	ADA-Negative Population		
Subject group type	Subject analysis set		
Number of subjects analysed	<b>59</b> <sup>[25]</sup>		
Units: Liters			
median (full range (min-max))	8.31 (4.57 to 23.77)		

Notes:

[25] - Range values are the 5th (min) and 95th (max) percentiles.

#### **Statistical analyses**

No statistical analyses for this end point

#### Secondary: PK: Maximum Serum Concentration (Cmax) of RO6958688

End point title	PK: Maximum Serum Concentration (Cmax) of RO6958688
End point description:	

End point type	Secondary
End point timeframe:	
Baseline up to 60 months	

End point values	40 mg-QW Cohort	80 mg-QW Cohort	100 mg-QW Cohort	160 mg-QW Cohort
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	117 <sup>[26]</sup>	5 <sup>[27]</sup>	26 <sup>[28]</sup>	42 <sup>[29]</sup>
Units: ug/mL				
median (full range (min-max))	12.06 (7.92 to 19.9)	18.51 (15.94 to 26.72)	26.72 (19.37 to 40.61)	39.27 (30.16 to 58.45)

Notes:

[26] - Range values are the 5th (min) and 95th (max) percentiles.

[27] - Range values are the 5th (min) and 95th (max) percentiles.

[28] - Range values are the 5th (min) and 95th (max) percentiles.

[29] - Range values are the 5th (min) and 95th (max) percentiles.

End point values	300 mg-QW Cohort	100 mg-Q3W Cohort	
Subject group type	Subject analysis set	Subject analysis set	
Number of subjects analysed	<b>3</b> <sup>[30]</sup>	20 <sup>[31]</sup>	

Clinical trial results 2015-003771-30 version 1

Units: ug/mL			
median (full range (min-max))	88.96 (70.02 to 102.95)	26.7 (13.77 to 47.89)	

Notes:

[30] - Range values are the 5th (min) and 95th (max) percentiles.

[31] - Range values are the 5th (min) and 95th (max) percentiles.

#### **Statistical analyses**

No statistical analyses for this end point

#### Secondary: PK: Clearance (CL) of RO6958688

End point title	PK: Clearance (CL) of RO6958688
End point description:	
End point type	Secondary

End point type	Secondary
End point timeframe:	
Baseline up to 60 months	

End point values	ADA-Negative Population		
Subject group type	Subject analysis set		
Number of subjects analysed	<b>59</b> <sup>[32]</sup>		
Units: L/h			
median (full range (min-max))	0.048 (0.026 to 0.113)		

Notes:

[32] - Range values are the 5th (min) and 95th (max) percentiles.

#### **Statistical analyses**

No statistical analyses for this end point

# Secondary: PK: Cmax of Atezolizumab End point title PK: Cmax of Atezolizumab End point description: End point type Secondary End point timeframe:

Baseline up to 60 months

End point values	Atezolizumab PK Population		
Subject group type	Subject analysis set		
Number of subjects analysed	180		
Units: ug/mL			
median (full range (min-max))	352 (69.4 to 690)		

No statistical analyses for this end point

#### Secondary: Percentage of Participants with Objective Response (Partial Response [PR] or Complete Response [CR] as Assessed Using Response Evaluation Criteria in Solid Tumors [RECIST])

End point title	Percentage of Participants with Objective Response (Partial
	Response [PR] or Complete Response [CR] as Assessed Using
	Response Evaluation Criteria in Solid Tumors [RECIST])

End point description:

End point type	Secondary
End point timeframe:	

End point timeframe:

Screening; every 8 weeks after the start of treatment for the first year, then every 12 weeks thereafter until disease progression or treatment discontinuation

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
number (not applicable)	0	12.5	15.4	0

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants				
number (not applicable)	15.0	0	5.1	0

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
number (not applicable)	0	0	0	0

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12		
Units: Percentage of Participants			
number (not applicable)	8.3		

No statistical analyses for this end point

# Secondary: Percentage of Participants with Disease Control (PR, CR, or Stable Disease [SD]) as Assessed Using RECIST

End point title	Percentage of Participants with Disease Control (PR, CR, or
	Stable Disease [SD]) as Assessed Using RECIST

End point description:

End point type

Secondary

End point timeframe:

Screening; every 8 weeks after the start of treatment for the first year, then every 12 weeks thereafter until disease progression or treatment discontinuation

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
number (not applicable)	35.3	50.0	53.8	100.0

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	150 mg CRC +	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35

Clinical trial results 2015-003771-30 version 1

Units: Percentage of Participants				
number (not applicable)	50.0	47.1	28.2	37.1

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
number (not applicable)	50.0	50.0	33.3	23.5

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12		
Units: Percentage of Participants			
number (not applicable)	41.7		

No statistical analyses for this end point

# Secondary: Percentage of Participants with Stable Disease (SD) as Assessed Using RECIST

Percentage of Participants with Stable Disease (SD) as
 Assessed Using RECIST

End point description:

End point type	Secondary

End point timeframe:

Screening; every 8 weeks after the start of treatment for the first year, then every 12 weeks thereafter until disease progression or treatment discontinuation

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
number (not applicable)	35.3	37.5	38.5	100.0

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants				
number (not applicable)	35.0	47.1	23.1	37.1

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
number (not applicable)	50.0	50.0	33.3	23.5

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12		
Units: Percentage of Participants			
number (not applicable)	33.3		

No statistical analyses for this end point

#### Secondary: Duration of Response (DOR) as Assessed Using RECIST

End point title	Duration of Response (DOR) as Assessed Using RECIST <sup>[33]</sup>
End point description:	

End point type

Secondary

End point timeframe:

From initial objective response (PR or CR to the first disease progression or death from any cause (up to 60 months)

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: This end point was specific to the groups reported.

End point values	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	39	20	39
Units: Months				
median (confidence interval 95%)	4.9 (3.8 to 6.9)	7.4 (3.7 to 28.6)	27.7 (3.6 to 27.7)	11.8 (6.0 to 17.6)

End point values	Gastric	All MAD CRC 100-160 mg QW + Q3W	
Subject group type	Reporting group	Subject analysis set	
Number of subjects analysed	12 <sup>[34]</sup>	83	
Units: Months			
median (confidence interval 95%)	20.3 (-9999 to 9999)	5.9 (3.8 to 27.7)	

Notes:

[34] - 9999 = CI was not evaluable

#### **Statistical analyses**

No statistical analyses for this end point

#### Secondary: Progression-Free Survival (PFS) according to RECIST V1.1

End point title	Progression-Free Survival (PFS) according to RECIST V1.1
End point description:	

End point description:

Secondary

End point timeframe:

End point type

From first study treatment to the first occurrence of objective disease progression or death from any cause (up to 60 months)

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1 <sup>[35]</sup>
Units: Months				
median (confidence interval 95%)	2.0 (1.6 to 7.0)	2.7 (1.9 to 3.7)	3.5 (1.9 to 3.7)	5.2 (0 to 9999)

Notes:

[35] - 9999 = No CI for single participant

	RO6958688	RO6958688	RO6958688	RO6958688
End point values	MAD 100 mg	Step Up B1 to	Step Up C1 to	Step Up C2 to

	Q3W CRC + Atezolizumab 1200 mg	1200 mg CRC + Atezolizumab 1200 mg	150 mg CRC + Atezolizumab 1200 mg	600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Months				
median (confidence interval 95%)	3.5 (2.1 to 3.8)	2.3 (2.0 to 3.1)	1.9 (1.7 to 3.0)	2.0 (1.9 to 3.6)

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Months				
median (confidence interval 95%)	2.8 (1.9 to 3.7)	2.8 (1.6 to 3.9)	1.9 (0.6 to 3.9)	1.7 (1.0 to 2.6)

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12		
Units: Months			
median (confidence interval 95%)	2.4 (1.2 to 9.0)		

No statistical analyses for this end point

Secondary: Overall Survival (OS)			
End point title	Overall Survival (OS)		
End point description:			
End point type	Secondary		

From first study treatment to death from any cause (up to 60 months)

RO6958688 RO6958688 RO6958688 RO6958688 MAD 5-80 mg MAD 100 mg MAD 160 mg MAD 300 mg End point values QW CRC + QW CRC + QW CRC + QW CRC + Atezolizumab Atezolizumab Atezolizumab Atezolizumab 1200 mg 1200 mg 1200 mg 1200 mg Reporting group Subject group type Reporting group Reporting group Reporting group 1[36] Number of subjects analysed 17 24 39 Units: Months 8.9 (5.0 to 12.4 (7.8 to 11.2 (7.1 to median (confidence interval 95%) 5.2 (0 to 9999) 18.8) 25.6) 13.7)

### Notes: [36] - 9999 = no CI for n=1

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab
	1200 mg	1200 mg	1200 mg	1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	<b>39</b> <sup>[37]</sup>	35
Units: Months				
median (confidence interval 95%)	8.6 (4.0 to 15.5)	10.4 (5.0 to 18.4)	11.1 (8.5 to 9999)	14.5 (7.7 to 18.4)

Notes:

[37] - 9999 = value not estimable

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2 <sup>[38]</sup>	3	17
Units: Months				
median (confidence interval 95%)	5.9 (5.1 to 6.7)	9999 (9999 to 9999)	13.0 (0.7 to 28.2)	5.5 (2.7 to 8.5)

Notes:

[38] - 9999 = insufficient participants with events

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12		
Units: Months			
median (confidence interval 95%)	3.9 (2.3 to 21.9)		

#### **Statistical analyses**

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)			
End point title	Best Overall Response (BOR)		
End point description:			
End point type	Secondary		
End point type End point timeframe:	Secondary		

End point values	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	24	39	1
Units: Percentage of Participants				
median (confidence interval 95%)				
Complete Response	0 (0.0 to 16.2)	0 (0.0 to 11.7)	2.6 (0.1 to 11.6)	0 (0.0 to 95.0)
Partial Response	0 (0.0 to 16.2)	12.5 (3.5 to 29.2)	12.8 (5.2 to 25.1)	0 (0.0 to 95.0)
Stable Disease	35.3 (16.6 to 58.0)	37.5 (21.2 to 56.3)	38.5 (25.4 to 52.9)	100.0 (5.0 to 100.0)

End point values	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg	RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	17	39	35
Units: Percentage of Participants				
median (confidence interval 95%)				
Complete Response	0 (0.0 to 13.9)	0 (0.0 to 16.2)	0 (0.0 to 7.4)	0 (0.0 to 8.2)
Partial Response	15.0 (4.2 to 34.4)	0 (0.0 to 16.2)	5.1 (0.9 to 15.3)	0 (0.0 to 8.2)
Stable Disease	35.0 (17.7 to 55.8)	47.1 (26.0 to 68.9)	23.1 (12.6 to 36.8)	37.1 (23.6 to 52.4)

End point values	Bile Duct	Breast	Lung	Pancreatic
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	17
Units: Percentage of Participants				
median (confidence interval 95%)				
Complete Response	0 (0.0 to 77.6)	0 (0.0 to 77.6)	0 (0.0 to 63.2)	0 (0.0 to 16.2)
Partial Response	0 (0.0 to 77.6)	0 (0.0 to 77.6)	0 (0.0 to 63.2)	0 (0.0 to 16.2)
Stable Disease	50.0 (2.5 to 97.5)	50.0 (2.5 to 97.5)	33.3 (1.7 to 86.5)	23.5 (8.5 to 46.1)

End point values	Gastric		
Subject group type	Reporting group		
Number of subjects analysed	12		
Units: Percentage of Participants			
median (confidence interval 95%)			
Complete Response	0 (0.0 to 22.1)		

Partial Response	8.3 (0.4 to 33.9)		
Stable Disease	33.3 (12.3 to 60.9)		

No statistical analyses for this end point

Timeframe for reporting adverse events:         Baseline up to 60 months         Assessment type       Non-systematic         Dictionary used         Dictionary name       MedDRA         Dictionary version       22.1         Reporting group title       R06958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 1V (intravenous) R06958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).         Reporting group title       R06958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 100 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 160 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 30 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 100 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 100 mg of IV R06958688 QW on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Parti	Adverse events information	
Assessment type         Non-systematic           Dictionary used         MedDRA           Dictionary version         22.1           Reporting groups         Reporting group description:           Participants received IV (Intravenous) RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:           Participants received IV (Intravenous) RO6958688 Meekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).           Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV RO6958688 QM on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Paro6958688 MD 1000 mg Q3W CRC + Atezolizumab 1200 mg	Timeframe for reporting adverse events	
Dictionary used         MedDRA           Dictionary version         22.1           Reporting groups         Reporting group description:           Participants received IV (intravenous) RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:           Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).           Reporting group title         RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received 100 mg of IV Atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV Atezolizumab Q3W.           Reporting group description:         Participants received 130 mg of IV Atezolizumab Q3W.           Reporting group description:         Participants received 300 mg of IV Ate20izumab Q3W.           Reporting group description:         Ro6958688 MD 300 mg QW CRC + Atezolizumab 1200 mg           Participants received 300 mg of IV Ro6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV Atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV Ro6958688 QW on Days 1 of each 21-day cycle, in combination with 1200 mg of IV Atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV Ro6958688 QW on Day 1 of each 21-day	Baseline up to 60 months	
Dictionary version         MedDRA           Dictionary version         22.1           Reporting groups         Reporting group description:           Participants received 1V (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of V atezolizumab every 3 weeks (Q3W).           Reporting group description:         Ro6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Ro6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg           Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Ro6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg           Reporting group duttle         RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group duttle         RO6958688 MD 100 mg QW CRC + Atezolizumab 1200 mg           Reporting group duttle         RO6958688 MD 100 mg QW CRC + Atezolizumab 1200 mg           Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 MD 100 mg Q3W CRC + Atezolizumab 1200 mg           Reporting group duttle         RO6958688 MD 100 mg Q3W CRC + Atezolizumab 1200 mg           Reporting group duttle         RO6958688 Step Up	Assessment type	Non-systematic
Dictionary version         22.1           Reporting groups         Reporting group title         RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (QW).           Reporting group title         RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received 100 mg of IV Atezolizumab Q3W.           Reporting group description:         RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Ro6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Ro6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group title         RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group title         RO6958688 Step Up C1 to 1200 mg CRC + Atezolizumab 1200 mg </td <td>Dictionary used</td> <td>•</td>	Dictionary used	•
Reporting groups           Reporting group description:           Participants received IV (intravenous) R06958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:           Participants received IV (intravenous) R06958688 Meekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (QW).           Reporting group title         R06958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received 100 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV Atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV Atezolizumab Q3W.           Reporting group description:         Participants received 300 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV R06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV R06958688 QW on Day 1 of each 21-day cycle, in combination with 1200 mg of IV R06958688 QW on Days 1 of each 21-day cycle, in combination with 1200 mg of IV R06958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg flv atezolizumab Q3W.           Reporting group title         R06958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg M2           Reporting group title         R06958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg M2	Dictionary name	MedDRA
Reporting group title         RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).           Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 Step Up D1 to 1200 mg CRC + Atezolizumab 1200 mg of IV at	Dictionary version	22.1
Reporting group description:       Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).         Reporting group description:       RA06958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg         Participants received 100 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 100 mg of IV RA06958688 QW up to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RA06958688 QW up to 1200 mg CRC + Atezolizumab 1200 mg of IV atezolizumab Q3W.         Reporting group title       RA06958688	Reporting groups	•
Reporting group description:       Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W).         Reporting group description:       RA06958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg         Participants received 100 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RA06958688 QW on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 100 mg of IV RA06958688 QW up to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RA06958688 QW up to 1200 mg CRC + Atezolizumab 1200 mg of IV atezolizumab Q3W.         Reporting group title       RA06958688	Reporting group title	RO6958688 MAD 5-80 mg QW CRC + Atezolizumab 1200 mg
Participants received IV (intravenous) RO6958688 weekly (QW) on Days 1, 8, and 15 of each 21-day cycle at escalating doses starting at 5 mg up to 80 mg, in combination with a fixed dose (1200 mg) of IV atezolizumab every 3 weeks (Q3W). Reporting group description: Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV RO6958688 QW on Days 1 of each 21-day cycle, in combination with 1200 mg of up description: Participants received 100 mg of IV RO6958688 QW on Day 1 of each 21-day cycle, in combination with 1200 mg of up tatezolizumab Q3W. Reporting group title Reporting group title Ro6958688 Step Up B1 to 1200 mg, then 1200 mg Q3W. Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants received increasing doses of IV RO6958688 QW up to 500 mg, then 150 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group title Reporting group title Reporting group description: Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group title Reporting group title Report		
Reporting group description:         Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Q3W on Days 1, 8, and 15 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C2 to 600 mg CK + Atezolizumab 1200 mg	cycle at escalating doses starting at 5 m	
Participants received 100 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 MD 160 mg QW CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 160 mg of IV Aceolizumab Q3W.         Reporting group description:       Ro6958688 MD 300 mg QW CRC + Atezolizumab 1200 mg         Reporting group description:       Ro6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV Aceolizumab Q3W.         Reporting group description:       Ro6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Reporting group description:         Participants received 100 mg of IV RO6958688 Q3W on Days 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Ro6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Participants received 100 mg of IV atezolizumab Q3W.       Reporting group title         Reporting group title       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 QW up to 1200 mg, then 1200 mg Q3W.         Participants received 1200 mg of IV atezolizumab Q3W.       Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.       Participants also received 1200 mg of IV atezolizumab Q3W.	Reporting group title	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg
combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.         Reporting group description:         Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W	Reporting group description:	
Reporting group description: Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received 300 mg of IV RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg Reporting group description: Participants received 100 mg of IV atezolizumab Q3W. Reporting group description: Participants received 100 mg of IV RO6958688 Q3W on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received 100 mg of IV RO6958688 Q3W up to 1200 mg CRC + Atezolizumab 1200 mg Reporting group description: Participants received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting g		
Participants received 160 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W. Reporting group title RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg Reporting group description: Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W. Reporting group title RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg Reporting group description: Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received 100 mg of IV RO6958688 Q3W up to 1200 mg CRC + Atezolizumab 1200 mg Reporting group description: Participants received 10200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group title RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received 1200	Reporting group title	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg         Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received 100 mg of IV RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 150 mg CRC + Atezolizumab 1200 mg       Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 150 mg CRC + Atezolizumab 1200 mg       Reporting group description:         Participants also received 1200 mg of IV atezolizumab Q3W.       Reporting group description:         Reporting group description:       Ro6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Ro6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title       Ro6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title       Bile Duct	Reporting group description:	
Reporting group description:         Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.         Participants received increasing doses of IV RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 150 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 Q		
Participants received 300 mg of IV RO6958688 QW on Days 1, 8, and 15 of each 21-day cycle in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received 100 mg of IV atezolizumab Q3W.         Participants received 1200 mg of IV atezolizumab Q3W.       Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group description:       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Ro6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Bile Duct       Bile Duct         Repor	Reporting group title	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg
combination with 1200 mg of IV atezolizumab Q3W.           Reporting group title         RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.           Reporting group title         RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg           Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.           Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group description:           Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.         Participants received 100 mg of IV atezolizumab Q3W.           Reporting group title         RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting Q3W.           Reporting group description:         Participants also received 1200 mg of IV atezolizumab Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.           Reporting group title         RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title           Reporting group description:         Participants also received 1200 mg of IV atezolizumab Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.           Reporting group title         Bile Duct         Bile Duct         Reporting group title         Bile Duct	Reporting group description:	
Reporting group description:         Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       Reporting group title       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg       Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.       Participants received increasing doses of IV RO6958688 QW up to 500 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Ro6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Bile Duct         Reporting group title       Bile Duct <td< td=""><td></td><td></td></td<>		
Participants received 100 mg of IV RO6958688 Q3W on Day 1 of each 21-day cycle, in combination with 1200 mg of IV atezolizumab Q3W.         Reporting group title       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       Reporting group title       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.       Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       Ro6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Bile Duct         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg,	Reporting group title	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg
1200 mg of IV atezolizumab Q3W.       RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.       Reporting group title         Reporting group title       RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Bile Duct       Reporting group title         Reporting group title       Bile Duct       Reporting group title         Reporting group title       Breast       Reporting group title         Reporting group title       Breast       Reporting group description:         Participants received increasing doses of	Reporting group description:	
mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleRO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.Participants received 1200 mg of IV atezolizumab Q3W.Reporting group titleRO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mgReporting group titleRO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Bile DuctReporting group description:Bile DuctParticipants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBreastReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. <t< td=""><td></td><td>958688 Q3W on Day 1 of each 21-day cycle, in combination with</td></t<>		958688 Q3W on Day 1 of each 21-day cycle, in combination with
Participants received increasing doses of IV RO6958688 QW up to 1200 mg, then 1200 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleRO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mgReporting group description: Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleRO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mgReporting group description: Participants received increasing doses of IV RO6958688 QW up to 600 mg CRC + Atezolizumab 1200 mgReporting group description: Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group description: Participants also received 1200 mg of IV atezolizumab Q3W. Reporting group description: Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBile DuctReporting group description: Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBreastReporting group description: Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group description: Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received i	Reporting group title	
Participants also received 1200 mg of IV atezolizumab Q3W.       Reporting group title       RO6958688 Step Up C1 to 150 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       Ro6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group title       RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg         Reporting group description:       Ro6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Bile Duct         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       Reporting group description:         Participants also received 1200 mg of IV atezolizumab Q3W.       Reporting group title         Reporting group title       Breast         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Reporting group description:       Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. </td <td>Reporting group description:</td> <td></td>	Reporting group description:	
mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleRO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBile DuctReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group description:Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBreastReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.		
Participants received increasing doses of IV RO6958688 QW up to 150 mg, then 150 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleRO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBile DuctReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBile DuctReporting group description:Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBreastReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.	Reporting group title	
Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleRO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBile DuctReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants received 1200 mg of IV atezolizumab Q3W.Reporting group titleBile DuctReporting group titleBreastReporting group titleBreastReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	Reporting group description:	
mgReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBile DuctReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.Reporting group titleBreastReporting group description:Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.Participants also received 1200 mg of IV atezolizumab Q3W.		
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Bile Duct         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Breast         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.	Reporting group title	
Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Bile Duct         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       Breast         Reporting group description:       Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.       Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.       Participants also received 1200 mg of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.	Reporting group description:	
Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Breast         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.		
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Breast         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.		
Participants also received 1200 mg of IV atezolizumab Q3W.         Reporting group title       Breast         Reporting group description:         Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W.         Participants also received 1200 mg of IV atezolizumab Q3W.	Reporting group description:	
Reporting group description: Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.		
Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.	Reporting group title	Breast
Participants also received 1200 mg of IV atezolizumab Q3W.	Reporting group description:	
Reporting group title		
	Reporting group title	Lung

#### Reporting group description:

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Reporting group title	Pancreatic
Reporting group description:	

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab O3W.

Participants also received 1200 mg of IV	atezolizumad Q3W.
Reporting group title	Gastric
Reporting group description:	

Participants received increasing doses of IV RO6958688 QW up to 600 mg, then 600 mg Q3W. Participants also received 1200 mg of IV atezolizumab Q3W.

Serious adverse events	RO6958688 MAD 5- 80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 17 (35.29%)	17 / 24 (70.83%)	24 / 39 (61.54%)
number of deaths (all causes)	13	15	24
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

1		l	
deaths causally related to treatment / all	0/0	0 / 0	0/0
Lymphocele			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and			
unspecified (incl cysts and polyps) Malignant melanoma in situ			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to	0/0	0 / 0	0 / 1
treatment / all	.,	0,0	· · / -
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour fistulisation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour inflammation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to			
treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (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
Chills			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	2 / 17 (11.76%)	2 / 24 (8.33%)	4 / 39 (10.26%)
treatment / all	I	I	1
---	-----------------	------------------	------------------
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Psychotic disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications Fall			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	2 / 17 (11.76%)	10 / 24 (41.67%)	10 / 39 (25.64%)
occurrences causally related to treatment / all	2 / 2	19 / 19	14 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0/0

Blood bilirubin increased			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Cardiac arrest			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
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			
Cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to		0 / 0	
treatment / all Dyspnoea	0 / 0	0 / 0	0 / 0
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	1/1	1/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Нурохіа			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0/0	3/3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 aspiration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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	1		
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (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
Dysarthria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

1	1	I	
deaths causally related to treatment / all	0 / 0	0 / 0	0/0
Intracranial pressure increased	-,-	-,-	-, -
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	1/1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 17 (5.88%)	3 / 24 (12.50%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	1/1	3 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices haemorrhage	070	070	0,0
subjects affected / exposed	0 / 17 /0 000/ )	0 / 24 /0 00%)	0 / 20 / 0 00%
occurrences causally related to	0 / 17 (0.00%) 0 / 0	0 / 24 (0.00%) 0 / 0	0 / 39 (0.00%) 0 / 0
treatment / all deaths causally related to	o / o		
treatment / all	0 / 0	0 / 0	0/0
Gastrointestinal haemorrhage subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0/1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	3/3	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage		' 	' 
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (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
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vomiting			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 4	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 retention			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

1			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular	- , -	-,-	- , -
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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	0 / 17 (0 000/)	0 / 24 (0 00%)	0 / 39 (0.00%)
occurrences causally related to	0 / 17 (0.00%)	0 / 24 (0.00%)	
treatment / all deaths causally related to	0 / 0	0 / 0	0 / 0
treatment / all	0/0	0 / 0	0/0
Arthritis subjects affected / exposed			
	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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			
Biliary tract infection subjects affected / exposed	0 / 17 /0 000/	0 / 0 / 0 000/ )	
	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection subjects affected / exposed			
	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to	0 / 0	0 / 0	0 / 0

Clinical trial results 2015-003771-30 version 1

treatment / all			
deaths causally related to treatment / all Clostridium difficile infection	0 / 0	0 / 0	0 / 0
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
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 tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
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 candida			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
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 infection			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences causally related to treatment / all	0 / 0	0/1	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events		RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg
Total subjects affected by serious		

Clinical trial results 2015-003771-30 version 1

adverse events	-		
subjects affected / exposed	1 / 1 (100.00%)	14 / 20 (70.00%)	9 / 17 (52.94%)
number of deaths (all causes)	1	15	14
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1/1
deaths causally related to treatment / all	0 / 0	0 / 0	1/1
Lymphocele			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ subjects affected / exposed	0 / 1 (0.00%)	0 / 20 /0 00%)	0 ( 17 (0 000( )
-		0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour fistulisation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chills			
subjects affected / exposed	1/1(100.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	1/1	0/0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Psychotic disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	9 / 20 (45.00%)	5 / 17 (29.41%)
occurrences causally related to treatment / all	0 / 0	11 / 11	14 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	2 / 3	1/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Liver function test increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Нурохіа			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Organising pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0/1(0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lymph node pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Costraintating			
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed	0 / 1 (0 000()	0 / 20 /0 000/ )	
	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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	1		
subjects affected / exposed	1/1(100.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (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
Intestinal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 perforation		I	
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction subjects affected / exposed	0/1(0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage	-,-		
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 pain			

subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis	1	I	
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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			
Biliary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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	1		
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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	Ì	Ì	

subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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 candida			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
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		RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg	Bile Duct
Total subjects affected by serious adverse events			
subjects affected / exposed	22 / 39 (56.41%)	25 / 35 (71.43%)	1 / 2 (50.00%)
number of deaths (all causes)	20	20	2
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

I			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocele			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and			
unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour fistulisation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to			
treatment / all	0 / 0	0 / 0	0 / 0

1		I	I I
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour inflammation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1/1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 39 (5.13%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to	0 / 0	1/1	0 / 0

treatment / all			
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 39 (0.00%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sychiatric disorders			
Psychotic disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
njury, poisoning and procedural omplications			
Fall			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	18 / 39 (46.15%)	15 / 35 (42.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	21 / 21	19 / 19	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0/1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nvestigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
	1/1	0 / 0	0 / 0
occurrences causally related to treatment / all	,		

occurrences causally related to treatment / all deaths causally related to treatment / all0 / 00 / 0Blood alkaline phosphatase increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all deaths causally related to treatment / all0 / 00 / 00 / 0Blood bilirubin increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Blood bilirubin increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Blood bilirubin increased subjects affected / exposed0 / 00 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Occurrences causally related to treatment / all deaths causally related to0 / 00 / 00 / 2Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Occurrences causally related to treatment / all deaths causally related to0 / 00 / 00 / 2	2 (0.00%) 0 / 0
treatment / all0 / 00 / 0deaths causally related to treatment / all0 / 00 / 0Blood alkaline phosphatase increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 00 / 2deaths causally related to 	0 / 0
treatment / all0 / 00 / 0Blood alkaline phosphatase increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 00 / 2deaths causally related to treatment / all0 / 00 / 00 / 00 / 2Blood bilirubin increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0deaths causally related to treatment / all0 / 00 / 00 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all deaths causally related to treatment / all0 / 00 / 00 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2deaths causally related to treatment / all0 / 00 / 00 / 2deaths causally related to treatment / all0 / 00 / 00 / 2deaths causally related to treatment / all0 / 00 / 00 / 2Gamma-glutamyltransferase0 / 00 / 00 / 00 / 0	
subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0deaths causally related to treatment / all0 / 00 / 00 / 0Blood bilirubin increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 00 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Occurrences causally related to treatment / all0 / 00 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 00 / 00 / 0Gamma-glutamyltransferase0 / 00 / 00 / 00 / 0	0 / 0
occurrences causally related to treatment / all0 / 00 / 0deaths causally related to treatment / all0 / 00 / 0Blood bilirubin increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 00 / 2deaths causally related to treatment / all0 / 00 / 00 / 00 / 2Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 00 / 00 / 2Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2Gamma-glutamyltransferase0 / 00 / 00 / 00 / 0	2 (0.00%)
treatment / all0 / 00 / 0Blood bilirubin increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0deaths causally related to treatment / all0 / 00 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2Occurrences causally related to treatment / all0 / 00 / 00 / 2Occurrences causally related to treatment / all0 / 00 / 00 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2occurrences causally related to treatment / all0 / 00 / 00 / 2Gamma-glutamyltransferase0 / 00 / 00 / 00 / 0	0/0
subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0deaths causally related to treatment / all0 / 00 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0deaths causally related to treatment / all0 / 00 / 00 / 0occurrences causally related to treatment / all0 / 00 / 00 / 0Gamma-glutamyltransferase0 / 00 / 00 / 0	0 / 0
occurrences causally related to treatment / all0 / 00 / 0deaths causally related to treatment / all0 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)occurrences causally related to treatment / all0 / 00 / 0deaths causally related to treatment / all0 / 00 / 0occurrences causally related to treatment / all0 / 00 / 0deaths causally related to treatment / all0 / 00 / 0Gamma-glutamyltransferase0 / 00 / 0	
treatment / all   0 / 0   0 / 0     deaths causally related to treatment / all   0 / 0   0 / 0     Blood creatinine increased subjects affected / exposed   0 / 39 (0.00%)   0 / 35 (0.00%)   0 / 2     occurrences causally related to treatment / all   0 / 0   0 / 0   0 / 0   0 / 0     deaths causally related to treatment / all   0 / 0   0 / 0   0 / 0   0 / 0     Gamma-glutamyltransferase   0 / 0   0 / 0   0 / 0   0 / 0   0 / 0	2 (0.00%)
treatment / all0 / 00 / 0Blood creatinine increased subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)occurrences causally related to treatment / all deaths causally related to treatment / all0 / 00 / 0Gamma-glutamyltransferase0 / 00 / 0	0 / 0
subjects affected / exposed0 / 39 (0.00%)0 / 35 (0.00%)0 / 2occurrences causally related to treatment / all0 / 00 / 00 / 0deaths causally related to treatment / all0 / 00 / 00 / 0Gamma-glutamyltransferase0 / 00 / 00 / 0	0 / 0
occurrences causally related to treatment / all 0 / 0 0 / 0   deaths causally related to treatment / all 0 / 0 0 / 0   Gamma-glutamyltransferase 0 / 0 0 / 0	
treatment / all deaths causally related to treatment / all Gamma-glutamyltransferase	2 (0.00%)
treatment / all 0 / 0 0 / 0 Gamma-glutamyltransferase	0 / 0
Gamma-glutamyltransferase increased	0 / 0
subjects affected / exposed     0 / 39 (0.00%)     0 / 35 (0.00%)     0 / 2	2 (0.00%)
occurrences causally related to 0 / 0 0 / 0 0 / 0 treatment / all	0 / 0
deaths causally related to treatment / all0 / 00 / 0	0 / 0
Liver function test increased	
subjects affected / exposed     0 / 39 (0.00%)     0 / 35 (0.00%)     0 / 2	2 (0.00%)
occurrences causally related to 0 / 0 0 / 0 treatment / all	0 / 0
deaths causally related to treatment / all0 / 00 / 0	0 / 0
Urine output decreased	
subjects affected / exposed     0 / 39 (0.00%)     0 / 35 (0.00%)     0 / 2	2 (0.00%)
occurrences causally related to 0 / 0 0 / 0 0 / 0 treatment / all	0 / 0
deaths causally related to treatment / all0 / 00 / 0	0 / 0
Cardiac disorders	
Cardiac arrest	
subjects affected / exposed     0 / 39 (0.00%)     0 / 35 (0.00%)     0 / 2	2 (0.00%)
occurrences causally related to 0 / 0 0 / 0 treatment / all	0 / 0
deaths causally related to treatment / all 0 / 0 0 / 0	1

Left ventricular dysfunction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1/1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0/1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Нурохіа			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0/0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (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
Pneumonia aspiration			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders Central nervous system			
haemorrhage		a / a= /a	
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

I	1	I	
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0/1
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (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
Ascites			· · · · · ·
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 / 3 960/)	0 / 2 (0.00%)
		1 / 35 (2.86%)	
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0

deaths causally related to			
treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0/0	0/0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subileus			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (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
Upper gastrointestinal haemorrhage subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/0	0 / 0
deaths causally related to treatment / all	0 / 0	0/0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/0	0 / 0
deaths causally related to treatment / all	0 / 0	0/0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0

Cholangitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders Pruritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1/1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed	_ / /		
	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
0 / 0	0 / 0	0 / 0
0 / 0	0 / 0	0 / 0
0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
0 / 0	0 / 0	0 / 0
0 / 0	0 / 0	0 / 0
0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
0 / 0	0/1	0 / 0
0 / 0	0 / 0	0 / 0
1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
0 / 1	0 / 0	0 / 0
0 / 0	0 / 0	0 / 0
0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
0 / 0	0 / 0	0 / 0
0 / 0	0 / 0	0 / 0
1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
0 / 1	0/1	0 / 0
0 / 0	0 / 0	0 / 0
0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
0 / 0	0 / 0	0 / 0
0 / 0	0 / 0	0 / 0
0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
0 / 0	0 / 0	0 / 0
0 / 0	0 / 0	0 / 0
	0 / 0 0 / 39 (0.00%) 0 / 0 0 / 0 0 / 39 (0.00%) 0 / 0 1 / 39 (2.56%) 0 / 1 0 / 0 0 / 39 (0.00%) 0 / 0 1 / 39 (2.56%) 0 / 1 0 / 0 1 / 39 (2.56%) 0 / 1 0 / 0 1 / 39 (0.00%) 0 / 0	0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 39 (0.00%)     0 / 35 (0.00%)       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 1       0 / 0     0 / 1       0 / 0     0 / 1       0 / 0     0 / 0       1 / 39 (2.56%)     0 / 35 (0.00%)       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       1 / 39 (2.56%)     1 / 35 (2.86%)       0 / 1     0 / 1       0 / 0     0 / 0       0 / 1     0 / 1       0 / 0     0 / 0       0 / 39 (0.00%)     0 / 35 (0.00%)       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0 / 0     0 / 0       0

Urinary tract infection subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (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

Serious adverse events	Breast	Lung	Pancreatic
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	13 / 17 (76.47%)
number of deaths (all causes)	0	3	15
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (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
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocele			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peripheral ischaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour fistulisation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Psychotic disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0

deaths causally related to treatment / all	0/0	0/0	0 / 0
Injury, poisoning and procedural complications			
Fall subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	4 / 17 (23.53%)
occurrences causally related to treatment / all	1 / 1	0 / 0	5 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0/3(0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1/3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
---	---------------	---------------	-----------------
deaths causally related to	0.40	0 / 0	0 / 0
treatment / all Gamma-glutamyltransferase	0/0	0/0	0/0
increased	1	l	
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2/2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Нурохіа			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular	070		
coagulation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0/1
Lymph node pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0/0
Neutropenia	l		
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to	0/0	0 / 0	0/0
treatment / all	0,0	0,0	0,0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (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
Cerebral ischaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0/0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			, -
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo positional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	1/1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0/0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to	0 / 0	0 / 0	0 / 0

treatment / all			
deaths causally related to treatment / all Renal failure	0 / 0	0 / 0	0 / 0
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Pruritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

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	0 / 2 (0.00%)	0/3(0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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			
Biliary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Candida infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection	· ·		· · ·
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis E			
	1	I	ı I

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
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 candida			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Serious adverse events	Gastric		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 12 (66.67%)		
number of deaths (all causes)	10		
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Embolism			

subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypovolaemic shock			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphocele			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Superior vena cava syndrome			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour fistulisation			

subjects affected / exposed	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Tumour flare		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Tumour inflammation		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Tumour pain		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0/0	
deaths causally related to treatment / all	0 / 0	
Immune system disorders		1
Cytokine release syndrome		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
General disorders and administration site conditions		
Asthenia		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Chills		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0/0	
deaths causally related to treatment / all	0 / 0	
Fatigue	1	
subjects affected / exposed	0 / 12 (0.00%)	
	0/0	
occurrences causally related to treatment / all	0,0	

Malaise	I
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to	0 / 0
treatment / all	0,0
deaths causally related to treatment / all	0 / 0
Oedema peripheral	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Pain	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Pyrexia	
subjects affected / exposed	3 / 12 (25.00%)
occurrences causally related to treatment / all	3/3
deaths causally related to treatment / all	0 / 0
Psychiatric disorders	
Psychotic disorder	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Injury, poisoning and procedural complications	
Fall	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Infusion related reaction	
subjects affected / exposed	2 / 12 (16.67%)
occurrences causally related to treatment / all	2 / 2
deaths causally related to treatment / all	0 / 0
Procedural pneumothorax	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0

<b>-</b>		1	i
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to			
treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver function test increased		I	I
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
· · ·		1	1
Urine output decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		

deaths causally related to treatment / all	0 / 0		
Cardiac disorders	· · ·		
Cardiac arrest			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular dysfunction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Нурохіа			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Organising pneumonia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion		1	l İ
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to	0/0		
· · · · · · · · · · · · · · · · · · ·	1 8,8		

treatment / all	
deaths causally related to treatment / all	0 / 0
Pneumonia aspiration subjects affected / exposed	1 / 12 (8.33%)
occurrences causally related to	
treatment / all	0 / 1
deaths causally related to treatment / all	0 / 0
Pneumonitis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Pneumothorax	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Blood and lymphatic system disorders	
Anaemia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Bicytopenia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Disseminated intravascular coagulation	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Lymph node pain	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Neutropenia	
subjects affected / exposed	0 / 12 (0.00%)

occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Central nervous system haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ischaemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysarthria	1		
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial pressure increased		1	
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders		1	
Vertigo positional			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites	1		

subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Colitis	
subjects affected / exposed	1 / 12 (8.33%)
occurrences causally related to treatment / all	1 / 1
deaths causally related to treatment / all	0 / 0
Diarrhoea	
subjects affected / exposed	1 / 12 (8.33%)
occurrences causally related to treatment / all	1/1
deaths causally related to treatment / all	0 / 0
Enteritis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Gastric varices haemorrhage	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Gastrointestinal haemorrhage	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Intestinal obstruction	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to treatment / all	0 / 0
Intestinal perforation	
subjects affected / exposed	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0
deaths causally related to	
treatment / all	0 / 0
Large intestinal obstruction	
subjects affected / exposed	0 / 12 (0.00%)

occurrences causally related to	0 / 0		
treatment / all deaths causally related to			
treatment / all	0/0		
Rectal haemorrhage subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to	0 / 0		

treatment / all			
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholangitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Pruritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis		1	1
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain		1	1

	1	1	1 1
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Biliary tract infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile infection			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis E			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Systemic candida			i i
subjects affected / exposed	0 / 12 (0.00%)		

	occurrences causally related to reatment / all	0 / 0
	leaths causally related to reatment / all	0 / 0
Up	per respiratory tract infection	
9	subjects affected / exposed	0 / 12 (0.00%)
	occurrences causally related to reatment / all	0 / 0
	leaths causally related to reatment / all	0 / 0
Uri	nary tract infection	
9	subjects affected / exposed	0 / 12 (0.00%)
	occurrences causally related to reatment / all	0 / 0
	leaths causally related to reatment / all	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %				
Non-serious adverse events	RO6958688 MAD 5- 80 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 160 mg QW CRC + Atezolizumab 1200 mg	
Total subjects affected by non-serious adverse events				
subjects affected / exposed	17 / 17 (100.00%)	24 / 24 (100.00%)	38 / 39 (97.44%)	
Vascular disorders				
Deep vein thrombosis				
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)	
occurrences (all)	0	1	0	
Flushing				
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	0 / 39 (0.00%)	
occurrences (all)	1	1	0	
Hot flush				
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)	
occurrences (all)	0	2	0	
Hypertension				
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)	
occurrences (all)	0	1	1	
Hypotension				
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	2 / 39 (5.13%)	
occurrences (all)	0	6	3	
Jugular vein thrombosis				
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)	

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

occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Raynaud's phenomenon			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Neoplasms benign, malignant and			
unspecified (incl cysts and polyps) Haemangioma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
	0	0	0
Tumour flare			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	6 / 17 (35.29%)	1 / 24 (4.17%)	10 / 39 (25.64%)
occurrences (all)	7	3	23
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia subjects affected / exposed		4 / 24 /16 670/	16 / 20 / 41 020/
	10 / 17 (58.82%)	4 / 24 (16.67%)	16 / 39 (41.03%)
occurrences (all)	13	4	30
Catheter site pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)

occurrences (all)	0	0	0
Chest pain subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.30%)
Chills			
subjects affected / exposed	11 / 17 (64.71%)	8 / 24 (33.33%)	14 / 39 (35.90%)
occurrences (all)	19	17	29
Cyst			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	5 / 17 (29.41%)	13 / 24 (54.17%)	14 / 39 (35.90%)
occurrences (all)	8	18	80
Gait disturbance			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Gravitational oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	1	2	1
Malaise			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Mucosal dryness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	3
Non-cardiac chest pain			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)

occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 17 (0.00%)	5 / 24 (20.83%)	7 / 39 (17.95%)
occurrences (all)	0	6	10
Pain			
subjects affected / exposed	2 / 17 (11.76%)	3 / 24 (12.50%)	3 / 39 (7.69%)
occurrences (all)	3	3	3
Pyrexia			
subjects affected / exposed	13 / 17 (76.47%)	16 / 24 (66.67%)	17 / 39 (43.59%)
occurrences (all)	31	25	38
Swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Bradyphrenia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Insomnia			
subjects affected / exposed	1 / 17 (5.88%)	3 / 24 (12.50%)	2 / 39 (5.13%)
occurrences (all)	1	3	3
Mania			

occurrences (all)     0	subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
Panic attack subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Paranoia subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Paranoia subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Reproductive system and breast disorders     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Inclision site pain subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       Infusion related reaction subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (0.00%)       Infusion related reaction subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (0.00%)	occurrences (all)			
subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Paranola subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Reproductive system and breast disorders     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Penile rash subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Industry poisoning and procedural complications     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       Inclision site pain subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       occurrences (all)     0     0     2     30 / 39 (76.92%)       occurrences (all)     9     42     62       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     1 / 39 (2.56%)       occurrences (all)     1     0     1     39 (0.00%)     0       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.0		Ū.	Ŭ	Ŭ
occurrences (all)     0     0     0     0     0       Paranola subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Reproductive system and breast disorders     0     0     0     0       Penile rash subjects affected / exposed occurrences (all)     0     0     0     0       Prostatitis subjects affected / exposed occurrences (all)     0     0     0     0     0       Injury, poisoning and procedural complications     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Infusion related reaction subjects affected / exposed occurrences (all)     0     0     0     2     30 / 39 (76.92%)       Joint injury subjects affected / exposed occurrences (all)     0     12 / 24 (0.00%)     0 / 39 (0.00%)     2       Joint injury subjects affected / exposed occurrences (all)     0     12 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       Occurrences (all)     1				
Paranoia subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%) 0       Reproductive system and breast disorders     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%) 0       Penile rash subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%) 0       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%) 0       Injury, poisoning and procedural complications uncision site pain subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     2 / 39 (5.13%) 2       Infusion related reaction subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     30 / 39 (76.92%) 62       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%) 0       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%) 1     0 / 24 (0.00%) 0     1 / 39 (2.56%) 0       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%)       Investigations Activated partial thromboplastin time prolonged     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)	subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Reproductive system and breast disorders     0     0     0     0     0       Reproductive system and breast disorders     0     0     0     0     0     0       Subjects affected / exposed occurrences (all)     0     0     0     0     0     0       Prostatitis subjects affected / exposed occurrences (all)     0     17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Indixion site pain subjects affected / exposed occurrences (all)     0     0     0     0       Infusion related reaction subjects affected / exposed occurrences (all)     0     0     2     30 / 39 (76.92%)       Joint injury subjects affected / exposed occurrences (all)     0     12 / 24 (50.00%)     30 / 39 (76.92%)       O / 17 (0.00%)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)     0       Joint injury subjects affected / exposed occurrences (all)     0     1     0     0     0       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)	occurrences (all)	0	0	0
occurrences (all)     0     0     0     0       Reproductive system and breast disorders     0     0     0     0     0       Penile rash subjects affected / exposed occurrences (all)     0     0     0     0     0       Prostatitis subjects affected / exposed occurrences (all)     0     0     0     0     0       Injury, poisoning and procedural complications     0     0     0     0     0     0       Infusion related reaction subjects affected / exposed occurrences (all)     0     0     0     2     30     7.9 (0.00%)       0     0     0     0     0     0     0     0       Infusion related reaction subjects affected / exposed occurrences (all)     0     12 / 24 (50.00%)     30 / 39 (0.00%)     62       Joint injury subjects affected / exposed occurrences (all)     0     0     0     0     0       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (0.00%)       Investigations     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)       <	Paranoia			
Reproductive system and breast disorders     No     No     No     No       Penile rash subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Indision site pain subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       Infusion related reaction subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     12 / 24 (50.00%)     30 / 39 (76.92%)       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Investigations Activated partial thromboplastin time prolonged subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)	subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
disorders   Penile rash   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0   0   0   0     Prostatitis   subjects affected / exposed   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0   0   0   0     Investigations   Incision site pain   0 / 17 (0.00%)   0 / 24 (0.00%)   2 / 39 (5.13%)     occurrences (all)   0   0   0   2     Infusion related reaction   0 / 17 (0.00%)   0 / 24 (0.00%)   2 / 39 (5.13%)     occurrences (all)   0   0   2   30 / 39 (76.92%)     occurrences (all)   9   42   62     Joint injury   subjects affected / exposed   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0   0   0   0     Procedural pain   subjects affected / exposed   1 / 17 (5.88%)   0 / 24 (0.00%)   1 / 39 (2.56%)     occurrences (all)   1   0   1   0   0     Skin abrasion   subjects affected / exposed   1 / 17 (5	occurrences (all)	0	0	0
subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Infury, poisoning and procedural complications Incision site pain subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       occurrences (all)     0     0     0     2       Infusion related reaction subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       occurrences (all)     0     0     2     30 / 39 (76.92%)       occurrences (all)     9     42     62       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       subjects affected / exposed occurrences (all)     1     0     0     0       Investigations subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Investigations subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0				
occurrences (all)     0     0     0     0     0       Prostatitis subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%) 0       Infury, poisoning and procedural complications Incision site pain subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     2 / 39 (5.13%) 0       Infusion related reaction subjects affected / exposed occurrences (all)     6 / 17 (35.29%) 9     12 / 24 (50.00%) 42     30 / 39 (76.92%) 62       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%) 0       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%) 1     0 / 24 (0.00%) 0     1 / 39 (2.56%) 0       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%) 0     0 / 24 (0.00%) 0     0 / 39 (0.00%)       Investigations Activated partial thromboplastin time prolonged subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)				
Prostatitis     Subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)     0       Injury, poisoning and procedural complications     0 / 17 (0.00%)     0	subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Injury, poisoning and procedural complications     0     0     0     0       Injury, poisoning and procedural complications     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       Incision site pain subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       Infusion related reaction subjects affected / exposed occurrences (all)     6 / 17 (35.29%)     12 / 24 (50.00%)     30 / 39 (76.92%)       occurrences (all)     9     42     62       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       occurrences (all)     1     0     1     0     1       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Investigations Activated partial thromboplastin time prolonged     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)	occurrences (all)	0	0	0
subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Injury, poisoning and procedural complications     0     0     0     0       Injury, poisoning and procedural complications     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       Incision site pain subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       Infusion related reaction subjects affected / exposed occurrences (all)     6 / 17 (35.29%)     12 / 24 (50.00%)     30 / 39 (76.92%)       occurrences (all)     9     42     62       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       occurrences (all)     1     0     1     0     1       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Investigations Activated partial thromboplastin time prolonged     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)	Prostatitis			
occurrences (all)     0     0     0       Injury, poisoning and procedural complications     Incision site pain subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       occurrences (all)     0     0     2     30 / 39 (5.13%)       occurrences (all)     0     0     2     30 / 39 (76.92%)       occurrences (all)     9     42     62       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       occurrences (all)     0     0     0     0     0       Procedural pain subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       occurrences (all)     1     0     1     0     1       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)       occurrences (all)     1     0     0     0       Investigations Activated partial thromboplastin time prolonged     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)		0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
Injury, poisoning and procedural complications000239 (5.13%)Incision site pain subjects affected / exposed occurrences (all)00022Infusion related reaction subjects affected / exposed occurrences (all)6 / 17 (35.29%) 912 / 24 (50.00%) 4230 / 39 (76.92%)Joint injury subjects affected / exposed occurrences (all)0 / 17 (0.00%) 90 / 24 (0.00%) 00 / 39 (0.00%)Procedural pain subjects affected / exposed occurrences (all)01 / 17 (5.88%) 10 / 24 (0.00%)1 / 39 (2.56%)Skin abrasion subjects affected / exposed occurrences (all)1 / 17 (5.88%) 10 / 24 (0.00%)0 / 39 (0.00%)Investigations Activated partial thromboplastin time prolonged0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	occurrences (all)			
complications     0 / 17 (0.00%)     0 / 24 (0.00%)     2 / 39 (5.13%)       occurrences (all)     0     0     2       Infusion related reaction     0 / 17 (0.00%)     12 / 24 (50.00%)     30 / 39 (76.92%)       occurrences (all)     9     42     62       Joint injury     9     42     62       Joint injury     0     0     0     0       subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       occurrences (all)     0     0     0     0       Procedural pain     subjects affected / exposed     1 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       occurrences (all)     1     0     1     30     39 (0.00%)       subjects affected / exposed     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)       occurrences (all)     1     0     1     0       Investigations     Activated partial thromboplastin time prolonged     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)		0	Ū	U
subjects affected / exposed   0 / 17 (0.00%)   0 / 24 (0.00%)   2 / 39 (5.13%)     occurrences (all)   0   0   2     Infusion related reaction   6 / 17 (35.29%)   12 / 24 (50.00%)   30 / 39 (76.92%)     occurrences (all)   9   42   62     Joint injury   9   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0   0   0   0     Procedural pain   subjects affected / exposed   1 / 17 (5.88%)   0 / 24 (0.00%)   1 / 39 (2.56%)     occurrences (all)   1   0   1   0   1     Skin abrasion   subjects affected / exposed   1 / 17 (5.88%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   1   0   0   0   0     Investigations   Activated partial thromboplastin time prolonged   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)				
occurrences (all)   0   0   2     Infusion related reaction subjects affected / exposed   6 / 17 (35.29%)   12 / 24 (50.00%)   30 / 39 (76.92%)     occurrences (all)   9   42   62     Joint injury subjects affected / exposed   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0   0   0     Procedural pain subjects affected / exposed   1 / 17 (5.88%)   0 / 24 (0.00%)   1 / 39 (2.56%)     occurrences (all)   1   0   1     Skin abrasion subjects affected / exposed   1 / 17 (5.88%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   1   0   1   0   1     Skin abrasion subjects affected / exposed   1 / 17 (5.88%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   1   0   0   0     Investigations Activated partial thromboplastin time prolonged   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)	·			
Infusion related reaction subjects affected / exposed occurrences (all)     6 / 17 (35.29%)     12 / 24 (50.00%)     30 / 39 (76.92%)       Joint injury subjects affected / exposed occurrences (all)     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Procedural pain subjects affected / exposed occurrences (all)     0 / 17 (5.88%)     0 / 24 (0.00%)     1 / 39 (2.56%)       Skin abrasion subjects affected / exposed occurrences (all)     1 / 17 (5.88%)     0 / 24 (0.00%)     0 / 39 (0.00%)       Investigations Activated partial thromboplastin time prolonged subjects affected / exposed     0 / 17 (0.00%)     0 / 24 (0.00%)     0 / 39 (0.00%)	subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
subjects affected / exposed   6 / 17 (35.29%)   12 / 24 (50.00%)   30 / 39 (76.92%)     occurrences (all)   9   42   62     Joint injury   subjects affected / exposed   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0   0   0   0     Procedural pain   1 / 17 (5.88%)   0 / 24 (0.00%)   1 / 39 (2.56%)     occurrences (all)   1   0   1     Skin abrasion   1 / 17 (5.88%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   1   0   0     Investigations   Activated partial thromboplastin time prolonged   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)	occurrences (all)	0	0	2
occurrences (all)   9   42   62     Joint injury subjects affected / exposed occurrences (all)   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     Procedural pain subjects affected / exposed occurrences (all)   1 / 17 (5.88%)   0 / 24 (0.00%)   1 / 39 (2.56%)     Skin abrasion subjects affected / exposed occurrences (all)   1   0   1     Skin abrasion subjects affected / exposed occurrences (all)   1 / 17 (5.88%)   0 / 24 (0.00%)   0 / 39 (0.00%)     Investigations Activated partial thromboplastin time prolonged subjects affected / exposed   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)				
Joint injury   subjects affected / exposed   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   0   0   0   0   0     Procedural pain   subjects affected / exposed   1 / 17 (5.88%)   0 / 24 (0.00%)   1 / 39 (2.56%)     occurrences (all)   1   0   1     Skin abrasion   1 / 17 (5.88%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   1   0   1     Skin abrasion   1 / 17 (5.88%)   0 / 24 (0.00%)   0 / 39 (0.00%)     occurrences (all)   1   0   0     Investigations   1 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)     Activated partial thromboplastin time prolonged   0 / 17 (0.00%)   0 / 24 (0.00%)   0 / 39 (0.00%)	subjects affected / exposed	6 / 17 (35.29%)	12 / 24 (50.00%)	30 / 39 (76.92%)
subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)0000Procedural pain subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)1 / 39 (2.56%)occurrences (all)101Skin abrasion subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)1000Investigations Activated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	occurrences (all)	9	42	62
occurrences (all)000Procedural pain subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)1 / 39 (2.56%)occurrences (all)101Skin abrasion subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)100Investigations Activated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	Joint injury			
Procedural pain subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)1 / 39 (2.56%)occurrences (all)101Skin abrasion subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)1000Investigations Activated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)1 / 39 (2.56%)occurrences (all)101Skin abrasion subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)1000Investigations Activated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	occurrences (all)	0	0	0
subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)1 / 39 (2.56%)occurrences (all)101Skin abrasion subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)1000Investigations Activated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	Procedural pain			
occurrences (all)101Skin abrasion subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)100Investigations Activated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)		1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)100InvestigationsActivated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	occurrences (all)			
subjects affected / exposed1 / 17 (5.88%)0 / 24 (0.00%)0 / 39 (0.00%)occurrences (all)100InvestigationsActivated partial thromboplastin time prolonged subjects affected / exposed0 / 17 (0.00%)0 / 24 (0.00%)0 / 39 (0.00%)	Skin abrasion			
occurrences (all) 1 0 0   Investigations Activated partial thromboplastin time prolonged 0 / 17 (0.00%) 0 / 24 (0.00%) 0 / 39 (0.00%)		1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
Activated partial thromboplastin time prolonged subjects affected / exposed 0 / 17 (0.00%) 0 / 24 (0.00%) 0 / 39 (0.00%)	occurrences (all)			
Activated partial thromboplastin time prolonged subjects affected / exposed 0 / 17 (0.00%) 0 / 24 (0.00%) 0 / 39 (0.00%)	Try contractions			
subjects affected / exposed 0 / 17 (0.00%) 0 / 24 (0.00%) 0 / 39 (0.00%)	Activated partial thromboplastin time			
		0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
	occurrences (all)			
		0	, v	Ŭ

			1
Alanine aminotransferase increased			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	4 / 39 (10.26%)
occurrences (all)	1	1	5
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 17 (23.53%)	2 / 24 (8.33%)	4 / 39 (10.26%)
occurrences (all)	6	4	5
Diago albumin degraped			
Blood albumin decreased subjects affected / exposed	0 ( 17 (0 000( )	0 ( 24 (0 00%)	0 / 20 /0 000/ )
	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
Blood bilirubin increased			
subjects affected / exposed	2 / 17 (11.76%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)			
	2	0	2
Blood creatine phosphokinase			
increased subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)			
	0	0	0
Blood creatinine increased			
subjects affected / exposed	2 / 17 (11.76%)	4 / 24 (16.67%)	1 / 39 (2.56%)
occurrences (all)	3	9	1
Blood fibrinogen decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 17 (17.65%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	3	1	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			

subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	6	0
Platelet count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	7
Serum ferritin decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	3 / 17 (17.65%)	3 / 24 (12.50%)	1 / 39 (2.56%)
occurrences (all)	3	3	1
White blood cell count decreased			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Atrial fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Bradycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)			
	0	0	3
Ventricular fibrillation			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0

Respiratory, thoracic and mediastinal disorders			
Aphonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
	, , , , , , , , , , , , , , , , , , ,	C C	_
Asthma			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	2	1	0
	2	I	0
Catarrh			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
		-	-
Cough			
subjects affected / exposed	7 / 17 (41.18%)	3 / 24 (12.50%)	9 / 39 (23.08%)
occurrences (all)	11	4	12
Dysphonia			
subjects affected / exposed	0 / 17 (0.00%)	6 / 24 (25.00%)	7 / 39 (17.95%)
occurrences (all)	0	6	8
Dyspnoea			
subjects affected / exposed	4 / 17 (23.53%)	2 / 24 (8.33%)	2 / 39 (5.13%)
occurrences (all)	6	2	2
Epistaxis			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
	Ŭ	-	U
Нурохіа			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Nasal congestion			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)			
	4	1	5
Oropharyngeal pain			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	3 / 39 (7.69%)
occurrences (all)	0	3	3
Pleural effusion subjects affected / exposed			
	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)

occurrences (all)	1	0	1
Pneumonitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Sputum discoloured			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Upper-airway cough			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Disadan di kumulati santan di sudan			
Blood and lymphatic system disorders Anaemia			
subjects affected / exposed	4 / 17 (23.53%)	4 / 24 (16.67%)	14 / 39 (35.90%)
occurrences (all)	4	4	22
Lymphopenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
	Ŭ	-	-
Thrombocytopenia			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	2 / 39 (5.13%)
occurrences (all)	0	1	2
Thrombocytosis			

subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Dizziness			
subjects affected / exposed	1 / 17 (5.88%)	4 / 24 (16.67%)	3 / 39 (7.69%)
occurrences (all)	1	5	3
Dysaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	10
	0	0	10
Dysarthria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 17 (11.76%)	13 / 24 (54.17%)	21 / 39 (53.85%)
occurrences (all)	2	14	23
Headache			
subjects affected / exposed	3 / 17 (17.65%)	6 / 24 (25.00%)	3 / 39 (7.69%)
occurrences (all)	4	8	4
Hemianopia homonymous subjects affected / exposed	0 / 17 (0 00%)	0 ( 24 (0 000( )	
	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Monoparesis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Nouropathy parinharal			
Neuropathy peripheral subjects affected / exposed	0 / 17 (0.00%)	1 / 2/ // 170/)	0 / 39 (0.00%)
occurrences (all)	0 / 17 (0.00%)	1 / 24 (4.17%) 1	0 / 39 (0.00%)
	Ĭ		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1

Psychomotor hyperactivity			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	3
Paraesthesia			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	2 / 39 (5.13%)
occurrences (all)	0	7	5
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	3 / 39 (7.69%)
occurrences (all)	0	1	4
Eye pruritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
		0	2
Lacrimation increased			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	3 / 39 (7.69%)
occurrences (all)	0	2	3
Orbital myositis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0 / 24 (0.00 %)	
		U	0
Vision blurred			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)

occurrences (all)	0	0	2
Ear and labyrinth disorders			
Vertigo subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0 / 24 (0.00 %)	1 1
Abdominal pain			
subjects affected / exposed	6 / 17 (35.29%)	5 / 24 (20.83%)	11 / 39 (28.21%)
occurrences (all)	8	14	12
Abdominal pain upper			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)	1	1	6
Abdominal tenderness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Atrophic glossitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	2 / 17 (11.76%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	2	0	2
Constipation			
subjects affected / exposed	4 / 17 (23.53%)	3 / 24 (12.50%)	7 / 39 (17.95%)

occurrences (all)	4	6	7
Diarrhoea			
subjects affected / exposed	9 / 17 (52.94%)	14 / 24 (58.33%)	26 / 39 (66.67%)
occurrences (all)	37	25	53
Dry mouth			
subjects affected / exposed	2 / 17 (11.76%)	5 / 24 (20.83%)	8 / 39 (20.51%)
occurrences (all)	2	6	30
Dyspepsia			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	2 / 39 (5.13%)
occurrences (all)	1	4	3
Dysphagia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	3 / 39 (7.69%)
occurrences (all)	0	0	7
Gastritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Gastrointestinal pain			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)	0	0	2
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	5 / 17 (29.41%)	8 / 24 (33.33%)	12 / 39 (30.77%)

occurrences (all)	8	16	19
Odynophagia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Rectal haemorrhage			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	1	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)	5	2	7
Toothache			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 17 (29.41%)	5 / 24 (20.83%)	15 / 39 (38.46%)
occurrences (all)	6	8	18
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Anuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	2 / 39 (5.13%)
occurrences (all)	0	1	3
Leukocyturia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
		U	U
Nephritis			
subjects affected / exposed		0 / 24 (0.00%)	0 / 39 (0.00%)
	0 / 17 (0.00%)	0 / 24 (0.00%)	07 33 (0.0070)
occurrences (all)	0 / 17 (0.00%)	0	0

subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Polyuria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Proteinuria subjects affected / exposed			
	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	2 / 17 (11.76%)	2 / 24 (8.33%)	11 / 39 (28.21%)
occurrences (all)	3	2	12
Erythema			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hair colour changes			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	0	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 17 (0.00%)	3 / 24 (12.50%)	0 / 39 (0.00%)
occurrences (all)	0	4	0
Hypohidrosis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
	U U	Ŭ	-
Palmar-plantar erythrodysaesthaesia syndrome			
subjects affected / exposed	0 / 17 (0.00%)	7 / 24 (29.17%)	4 / 39 (10.26%)

Papule subjects affected / exposed occurrences (all) Pruritis	0 / 17 (0.00%) 0	0 / 24 (0.00%) 0	0 / 39 (0.00%)
subjects affected / exposed occurrences (all) Pruritis			
Pruritis	0	0	
			0
subjects affected / exposed	4 / 17 (23.53%)	5 / 24 (20.83%)	10 / 39 (25.64%)
occurrences (all)	6	5	11
Rash			
subjects affected / exposed	1 / 17 (5.88%)	5 / 24 (20.83%)	2 / 39 (5.13%)
occurrences (all)	1	6	3
Rash erythematous			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	6 / 39 (15.38%)
occurrences (all)	1	2	6
Rash pruritic			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	2 / 17 (11.76%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	2	2	1
Skin lesion			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Color dormatitie			
Solar dermatitis subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1 (5.88%)	0 / 24 (0.00%)	07 39 (0.00%)
Urticaria			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0 / 1 / (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
	-	-	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 17 (0.00%)	6 / 24 (25.00%)	15 / 39 (38.46%)
occurrences (all)	0	9	34

Arthritis	1	I	I
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	4 / 39 (10.26%)
occurrences (all)		0	8
		0	0
Back pain			
subjects affected / exposed	5 / 17 (29.41%)	6 / 24 (25.00%)	7 / 39 (17.95%)
occurrences (all)	5	8	10
Dactylitis subjects affected / exposed	0 ( 17 (0 000())		
	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Immune-mediated arthritis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
		0	0
Muscle contracture			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)			
	0	2	0
Muscular weakness			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
<b></b>			
Musculoskeletal chest pain subjects affected / exposed	0 / 17 (0 000/)	0 ( 24 (0 000( )	
	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	2 / 39 (5.13%)
occurrences (all)	1	2	2
Myalgia			
subjects affected / exposed	2 / 17 (11.76%)	3 / 24 (12.50%)	3 / 39 (7.69%)
occurrences (all)	2	4	3
		l	
Neck pain			
------------------------------------	-----------------	-----------------	------------------
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	1 / 39 (2.56%)
occurrences (all)	0	2	1
Spondylitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Hypothyroidism			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 17 (17.65%)	9 / 24 (37.50%)	14 / 39 (35.90%)
occurrences (all)	3	10	19
Dehydration			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)			
	0	0	1
Diabetes mellitus			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	2 / 39 (5.13%)
occurrences (all)			
	3	0	2
Hyperkalaemia			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)

occurrences (all)	1	0	1
Hypertriglyceridaemia subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	3 / 39 (7.69%)
occurrences (all)	0	2	3
Hypocalcaemia subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
Hypomagnasaemia subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	0 / 39 (0.00%)
occurrences (all)	0	1	0
Polydipsia subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitamin B6 deficiency subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia subjects affected / exposed	1 / 17 (5.88%)	3 / 24 (12.50%)	1 / 39 (2.56%)
occurrences (all)	1	6	1
Hypophosphataemia			
subjects affected / exposed	1 / 17 (5.88%)	4 / 24 (16.67%)	0 / 39 (0.00%)

occurrences (all)	1	7	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	2 / 17 (11.76%)	1 / 24 (4.17%)	4 / 39 (10.26%)
occurrences (all)	2	1	9
Influenza			
subjects affected / exposed	0 / 17 (0.00%)	1 / 24 (4.17%)	1 / 39 (2.56%)
occurrences (all)			
	0	1	1
Lip infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)			
	1	0	1
Oral candidiasis			
subjects affected / exposed	1 / 17 (5.88%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	1	2	0
Oral herpes			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	0 / 17 (0.00%)	2 / 24 (8.33%)	0 / 39 (0.00%)
occurrences (all)	0	2	0
l			

Pharyngitis			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	1 / 39 (2.56%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	1 / 17 (5.88%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
Skin candida			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0 0 0	0 / 24 (0.00 %)	0 / 33 (0.00 %)
Upper respiratory tract infection subjects affected / exposed			
occurrences (all)	1 / 17 (5.88%)	2 / 24 (8.33%)	3 / 39 (7.69%)
		2	3
Urinary tract infection			
subjects affected / exposed	1 / 17 (5.88%)	1 / 24 (4.17%)	5 / 39 (12.82%)
occurrences (all)	1	1	5
Varicella			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 17 (0.00%)	0 / 24 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
	l	l	l
Non-serious adverse events	RO6958688 MAD 300 mg QW CRC + Atezolizumab 1200 mg	RO6958688 MAD 100 mg Q3W CRC + Atezolizumab 1200 mg	RO6958688 Step Up B1 to 1200 mg CRC + Atezolizumab 1200 mg

adverse events subjects affected / exposed	1/1(100.00%)	20 / 20 (100.00%)	17 / 17 (100.00%
/ascular disorders	1/1(100.00%)	20 / 20 (100.00%)	17 / 17 (100.00%)
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	2 / 17 (11.76%)
occurrences (all)	0	3	2
Jugular vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Noonloome bonien, malianant and			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Tumour flare subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tumour pain subjects affected / exposed	1 / 1 (100.00%)	1 / 20 (5.00%)	2 / 17 (11.76%)
occurrences (all)	1	1	3
Immune system disorders Hypersensitivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions Asthenia			
subjects affected / exposed	1 / 1 (100.00%)	3 / 20 (15.00%)	10 / 17 (58.82%)
occurrences (all)	1	4	13
Catheter site pain subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Chills subjects affected / exposed	1 / 1 (100.00%)	7 / 20 (35.00%)	3 / 17 (17.65%)
occurrences (all)	1	10	4
Curch			
Cyst subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Fatigue subjects affected / exposed	0 / 1 (0.00%)	7 / 20 (35.00%)	4 / 17 (23.53%)
occurrences (all)	0	11	4
Gait disturbance subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0

	I	I	I
Gravitational oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Mucosal dryness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pyrexia subjects affected / exposed			
	1 / 1 (100.00%)	16 / 20 (80.00%)	4 / 17 (23.53%)
occurrences (all)	2	22	4
Swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

I	I	1	
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	
		2	0
Bradyphrenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Transmis			
Insomnia subjects affected / exposed			
	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Mania			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
			Ũ
Panic attack			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Paranoia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Poproductive system and breast			
Reproductive system and breast disorders			
Penile rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Prostatitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)			
	0	2	0
Injury, poisoning and procedural			
		•	

Clinical trial results 2015-003771-30 version 1

complications			
Incision site pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 1 (0.00%)	11 / 20 (55.00%)	14 / 17 (82.35%)
occurrences (all)	0	17	41
Joint injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Investigations Activated partial thromboplastin time			
prolonged			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	4 / 20 (20.00%)	2 / 17 (11.76%)
occurrences (all)	0	6	2
Aspartate aminotransferase			
increased subjects affected / exposed	0 / 1 (0.00%)	5 / 20 (25.00%)	3 / 17 (17.65%)
occurrences (all)	0 / 1 (0.00 /0)	10	3
	U	10	3
Blood albumin decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Blood creatine phosphokinase			

increased subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%
occurrences (all)	0	1	1
Blood fibrinogen decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%
occurrences (all)	0	1	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%
occurrences (all)	0	3	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%
occurrences (all)	0	0	1
Serum ferritin decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%
occurrences (all)	0	2	1
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0

Angina pectoris			
subjects affected / exposed	0/1(0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0/1(0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Atrial flutter			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Ventricular fibrillation subjects affected / exposed			
	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			
disorders Aphonia			
subjects affected / exposed	0/1(0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Asthma subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	3 / 17 (17.65%)
l ·	_ , _ (0.00,0)	-, _, (_0.00,0)	-, -: (-::00,0)

occurrences (all)	0	3	4
Dysphonia			
subjects affected / exposed	1/1(100.00%)	3 / 20 (15.00%)	3 / 17 (17.65%)
occurrences (all)	1	4	3
Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	3 / 17 (17.65%)
occurrences (all)	0	4	3
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Нурохіа			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	2
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	4
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
		0	0
Pneumonitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
		-	-
Sputum discoloured			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Upper-airway cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 1 (0.00%)	6 / 20 (30.00%)	3 / 17 (17.65%)
occurrences (all)	0	8	5
Lymphopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
I			

Dysgeusia subjects affected / exposed	0 / 1 (0.00%)	7 / 20 (35.00%)	4 / 17 (23.53%
occurrences (all)	0	8	8
Headache			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Hemianopia homonymous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%
occurrences (all)	0	0	1
Hyperaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Monoparesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%
occurrences (all)	0	2	0
e disorders			
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%

occurrences (all)	0	1	0
Eye pruritis subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Orbital myositis subjects affected / exposed occurrences (all)	0 / 1 (0.00%)	0 / 20 (0.00%) 0	1 / 17 (5.88%)
Devierbital swelling			_
Periorbital swelling subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Retinal artery occlusion subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	4 / 20 (20.00%)	4 / 17 (23.53%)
occurrences (all)	0	5	5

Abdominal pain upper subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Abdominal tenderness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Anal fissure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Atrophic glossitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	4 / 17 (23.53%)
occurrences (all)	0	3	4
Diarrhoea			
subjects affected / exposed	1 / 1 (100.00%)	14 / 20 (70.00%)	9 / 17 (52.94%)
occurrences (all)	2	24	16
	2	27	10
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1

Gastritis	l		
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Glossitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 1 (100.00%)	7 / 20 (35.00%)	2 / 17 (11.76%)
occurrences (all)	1	10	2
Odynophagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0

Vomiting subjects affected / exposed			
	1 / 1 (100.00%)	7 / 20 (35.00%)	4 / 17 (23.53%)
occurrences (all)	1	9	4
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Leukocyturia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Polyuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Portal vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Hair colour changes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypohidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthaesia			
syndrome subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	0 / 17 (0.00%)
occurrences (all)	0	3	0
Denula			
Papule subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
	Ŭ	Ŭ	Ŭ
Pruritis			
subjects affected / exposed	0 / 1 (0.00%)	7 / 20 (35.00%)	2 / 17 (11.76%)
occurrences (all)	0	8	3
Rash			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	4 / 17 (23.53%)
occurrences (all)	0	2	4
Rash erythematous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	2 / 17 (11.76%)
occurrences (all)	0	2	4

	l	I	
Rash pruritic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Skin exfoliation			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	6 / 17 (35.29%)
occurrences (all)	0	4	7
Skin lesion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue			
disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	4 / 20 (20.00%)	0 / 17 (0.00%)
occurrences (all)	0	7	0
Arthritis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	3
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	4	1
Dactylitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
	, v		, , , , , , , , , , , , , , , , , , ,
Immune-mediated arthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Joint swelling			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%)	1 / 20 (5.00%) 1	0 / 17 (0.00%)
	0	I	U
Muscle contracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	4 / 17 (23.53%)
occurrences (all)	0	0	5
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
			l l

Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 1 (100.00%)	9 / 20 (45.00%)	9 / 17 (52.94%)
occurrences (all)	2	9	13
Dehydration			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0 / 20 (0.00 %)	0
Hunachucacmia			
Hypoglycaemia subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	1 / 17 (5.88%)
occurrences (all)	0 / 1 (0.00%)	1 / 20 (5.00%)	1/1/(5.88%)
Hypokalaemia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)

occurrences (all)	0	2	4
Hypomagnasaemia subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Polydipsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Vitamin B12 deficiency subjects affected / exposed	0/1(0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vitamin B6 deficiency subjects affected / exposed	0/1(0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Vitamin D deficiency subjects affected / exposed			
	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	3 / 20 (15.00%)	1 / 17 (5.88%)
occurrences (all)	0	8	2
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1/1(100.00%)	2 / 20 (10.00%)	1 / 17 (5.88%)
occurrences (all)	1	2	1
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	1 / 20 (5.00%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lip infection			

subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paronychia subjects affected / exposed	0 ( 1 (0 000( )		0 ( 17 (0 000( )
occurrences (all)	0 / 1 (0.00%) 0	0 / 20 (0.00%) 0	0 / 17 (0.00%) 0
Pharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 20 (10.00%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Skin candida subjects affected / exposed	0 / 1 (0.00%)	0 / 20 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tooth abscess			

subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 20 (5.00%) 1	0 / 17 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	1 / 20 (5.00%) 2	0 / 17 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 20 (0.00%) 0	0 / 17 (0.00%) 0
Varicella subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 20 (0.00%) 0	1 / 17 (5.88%) 1
Vascular device infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 20 (0.00%) 0	0 / 17 (0.00%) 0
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0	0 / 20 (0.00%) 0	0 / 17 (0.00%) 0

Non-serious adverse events		RO6958688 Step Up C2 to 600 mg CRC + Atezolizumab 1200 mg	Bile Duct
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 39 (97.44%)	35 / 35 (100.00%)	2/2(100.00%)
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hot flush			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Hypotension			

subjects affected / exposed	3 / 39 (7.69%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
	5	±	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma subjects affected / exposed			- / - /
	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	8 / 39 (20.51%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	19	7	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)			
	0	0	0
General disorders and administration			
site conditions	I	I	l

Asthenia			
subjects affected / exposed	8 / 39 (20.51%)	7 / 35 (20.00%)	1 / 2 (50.00%)
occurrences (all)	12	12	1
Catheter site pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	9 / 39 (23.08%)	11 / 35 (31.43%)	1 / 2 (50.00%)
occurrences (all)	13	14	1
Cyst			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
	0	0	0
Fatigue			
subjects affected / exposed	16 / 39 (41.03%)	18 / 35 (51.43%)	0 / 2 (0.00%)
occurrences (all)	30	27	0
Gait disturbance			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	5 / 39 (12.82%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	5	3	0
	5	5	0
Malaise			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Mucocal inflammation			
Mucosal inflammation subjects affected / exposed		1 / 35 / 3 960/ )	
occurrences (all)	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
	I	I	

Non-cardiac chest pain	1		
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	4 / 39 (10.26%)	3 / 35 (8.57%)	1 / 2 (50.00%)
occurrences (all)	4	3	1
Pain			
subjects affected / exposed	3 / 39 (7.69%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
Pyrexia			
subjects affected / exposed	16 / 39 (41.03%)	15 / 35 (42.86%)	1 / 2 (50.00%)
occurrences (all)	22	24	2
Swelling subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2 / 39 (3.13%)		
	2	0	0
Temperature regulation disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Bradyphrenia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
			•

occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	1 / 39 (2.56%)	5 / 35 (14.29%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Mania			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Panic attack			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paranoia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Penile rash subjects affected / exposed			
	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Incision site pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	26 / 39 (66.67%)	18 / 35 (51.43%)	1 / 2 (50.00%)
occurrences (all)	68	37	6
Joint injury			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
		-	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	8 / 39 (20.51%)	7 / 35 (20.00%)	1 / 2 (50.00%)
occurrences (all)	12	8	1
Aspartate aminotransferase			
increased			
subjects affected / exposed	9 / 39 (23.08%)	9 / 35 (25.71%)	0 / 2 (0.00%)
occurrences (all)	15	10	0
Blood albumin decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	3 / 39 (7.69%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
	5		J J
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Blood fibrinogen decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
	5	Ŭ	, , , , , , , , , , , , , , , , , , ,
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	2 / 55 (5.15 %)	1	0
	2	1	0
Platelet count decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
	0	I	0
White blood cell count decreased subjects affected / exposed	_ / /		
	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bradycardia subjects affected / exposed			
	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Aphonia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Asthma subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Bronchospasm subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         12 / 39 (30.77%) 14         10 / 35 (28.57%) 10 / 35 (28.57%) 0         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 1           Dysphonia subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 5         4 / 35 (11.43%) 0         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         1 / 35 (2.86%) 0         0 / 2 (0.00%) 0	To durant d'a			
occurrences (all)         D / B (news)         D / B (news) <thd (news)<<="" td=""><td></td><td>1 / 30 (2 56%)</td><td>2 / 25 (5 7106)</td><td>0 / 2 (0 00%)</td></thd>		1 / 30 (2 56%)	2 / 25 (5 7106)	0 / 2 (0 00%)
subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Respiratory, thoracic and mediastinal disorders         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Aphonia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Bronchospasm subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         12 / 39 (30.77%) 14         10 / 35 (28.57%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 0         0 / 2 (0.00%) 1           Dysphonia subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 0         4 / 35 (11.43%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%)	-			
subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Respiratory, thoracic and mediastinal disorders         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Aphonia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Bronchospasm subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         12 / 39 (30.77%) 14         10 / 35 (28.57%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 0         0 / 2 (0.00%) 1           Dysphonia subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 0         4 / 35 (11.43%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0         0 / 2 (0.00%)	Ventricular fibrillation			
occurrences (all)         0         0         0         0         0           Respiratory, thoracic and mediastinal disorders         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           active affected / exposed         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           active affected / exposed         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           accurrences (all)         0         0         0         0           Bronchospasm subjects affected / exposed         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           occurrences (all)         0         0         0         0         0           Catarrh subjects affected / exposed         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)         0           occurrences (all)         0         0         0         0         0         0           Cough subjects affected / exposed         0 / 39 (0.00%)         10 / 35 (28.57%)         0 / 2 (0.00%)         0         2 (0.00%)           Dysphonia subjects affected / exposed         5 / 39 (15.38%)         5 / 35 (14.29%)         1 / 2 (50.00%)         0 / 2 (0.00%)           Dysphosea subjects affected / exposed         5 / 39 (12.82%)         4 / 35 (11.43%)         0 / 2 (0.00%)         0 / 2 (0		0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
disorders         instant	occurrences (all)			
disorders         instant	Despiratory, there is and mediactinal			
subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Asthma subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Bronchospasm subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         12 / 39 (30.77%) 14         10 / 35 (28.57%) 10 / 35 (28.57%) 6         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 1           Dyspnoea subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 5         4 / 35 (11.43%) 5         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         1 / 35 (2.86%) 0         0 / 2 (0.00%) 0	disorders			
occurrences (all)         0         0         0         0           Asthma subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Bronchospasm subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 12 / 39 (30.77%) 14         10 / 35 (28.57%) 13         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 5 / 35 (14.29%) 1 / 2 (50.00%) 0         1 / 2 (50.00%) 1 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 5 / 35 (14.29%) 0         1 / 2 (50.00%) 0           Dysphoea subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 5 / 35 (1.42%) 0         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         1 / 35 (2.86%) 0         0 / 2 (0.00%)	·			
Asthma subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Bronchospasm subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 14         0 / 35 (28.57%) 10 / 35 (28.57%) 0         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 1           Dysphonia subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 5         4 / 35 (11.43%) 5         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         1 / 35 (2.86%) 0 / 2 (0.00%)         0 / 2 (0.00%)	-	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Bronchospasm       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0       0       0       0         Catarrh       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)       0         Cough       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       12 / 39 (30.77%)       10 / 35 (28.57%)       0 / 2 (0.00%)         Dysphonia       subjects affected / exposed       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         occurrences (all)       6       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         Dysphoea       subjects affected / exposed       5 / 39 (12.82%)       4 / 35 (10.00%)       0 / 2 (0.00%)         ccurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)       0         Epistaxis       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%) <td>occurrences (all)</td> <td>0</td> <td>0</td> <td>0</td>	occurrences (all)	0	0	0
accurrences (all)       0       0       0       0         Bronchospasm subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Catarrh subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Cough subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Cough subjects affected / exposed occurrences (all)       12 / 39 (30.77%)       10 / 35 (28.57%)       0 / 2 (0.00%)         Dysphonia subjects affected / exposed occurrences (all)       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         Dysphonea subjects affected / exposed occurrences (all)       6 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         Dysphoea subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Epistaxis subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)				
Bronchospasm subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         12 / 39 (30.77%) 14         10 / 35 (28.57%) 10 / 35 (28.57%)         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 1           Dysphoea subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 5         4 / 35 (11.43%) 5         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         1 / 35 (2.86%) 0         0 / 2 (0.00%) 0	subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
subjects affected / exposed occurrences (all)         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           Cough subjects affected / exposed occurrences (all)         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           Cough subjects affected / exposed occurrences (all)         12 / 39 (30.77%)         10 / 35 (28.57%)         0 / 2 (0.00%)           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%)         5 / 35 (14.29%)         1 / 2 (50.00%)           Dysphoea subjects affected / exposed occurrences (all)         5 / 39 (12.82%)         4 / 35 (11.43%)         0 / 2 (0.00%)           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%)         0 / 35 (0.00%)         0 / 2 (0.00%)           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%)         0 / 35 (2.86%)         0 / 2 (0.00%)	occurrences (all)	0	0	0
occurrences (all)         0         0         0         0           Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         12 / 39 (30.77%) 14         10 / 35 (28.57%) 13         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 1           Dysphonia subjects affected / exposed occurrences (all)         5 / 39 (12.82%) 5         4 / 35 (11.43%) 5         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         1 / 35 (2.86%) 2         0 / 2 (0.00%) 0	Bronchospasm			
Catarrh subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Cough subjects affected / exposed occurrences (all)         12 / 39 (30.77%) 14         10 / 35 (28.57%) 13         0 / 2 (0.00%) 0           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 1           Dysphonia subjects affected / exposed occurrences (all)         6 / 39 (15.38%) 8         5 / 35 (14.29%) 6         1 / 2 (50.00%) 1           Dysphonea subjects affected / exposed occurrences (all)         6 / 39 (12.82%) 5         4 / 35 (11.43%) 5         0 / 2 (0.00%) 0           Epistaxis subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         0 / 35 (0.00%) 0         0 / 2 (0.00%) 0           Hypoxia subjects affected / exposed occurrences (all)         0 / 39 (0.00%) 0         1 / 35 (2.86%) 2         0 / 2 (0.00%) 0	subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Cough subjects affected / exposed occurrences (all)       12 / 39 (30.77%)       10 / 35 (28.57%)       0 / 2 (0.00%)         Dysphonia subjects affected / exposed occurrences (all)       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         Dysphonia subjects affected / exposed occurrences (all)       6 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         Dyspnoea subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Epistaxis subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)	occurrences (all)	0	0	0
occurrences (all)       0       0       0         occurrences (all)       0       0       0         Subjects affected / exposed occurrences (all)       12 / 39 (30.77%)       10 / 35 (28.57%)       0 / 2 (0.00%)         Dysphonia subjects affected / exposed occurrences (all)       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         Dyspnoea subjects affected / exposed occurrences (all)       6 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         Epistaxis subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)	Catarrh			
Cough subjects affected / exposed occurrences (all)       12 / 39 (30.77%)       10 / 35 (28.57%)       0 / 2 (0.00%)         Dysphonia subjects affected / exposed occurrences (all)       14       13       0         Dysphonia subjects affected / exposed occurrences (all)       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         Dyspnoea subjects affected / exposed occurrences (all)       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         Epistaxis subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         0       2       0       0       0       0	subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
subjects affected / exposed       12 / 39 (30.77%)       10 / 35 (28.57%)       0 / 2 (0.00%)         occurrences (all)       14       13       0         Dysphonia       subjects affected / exposed       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         occurrences (all)       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         Dysphoea       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         subjects affected / exposed       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         occurrences (all)       5       5       0       0         Epistaxis       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)       0         Hypoxia       subjects affected / exposed       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)       0         occurrences (all)       0       2       0       0       0       0       0	occurrences (all)	0	0	0
occurrences (all)       14       13       0         Dysphonia subjects affected / exposed occurrences (all)       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         Dyspnoea subjects affected / exposed occurrences (all)       6 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         Epistaxis subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (2.86%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         0       2       0	Cough			
Dysphonia subjects affected / exposed occurrences (all)       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         Dyspnoea subjects affected / exposed occurrences (all)       6 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         Epistaxis subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Hypoxia subjects affected / exposed occurrences (all)       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         0       2       0	subjects affected / exposed	12 / 39 (30.77%)	10 / 35 (28.57%)	0 / 2 (0.00%)
subjects affected / exposed       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         occurrences (all)       8       6       1         Dyspnoea       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         occurrences (all)       5       5       0         Epistaxis       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0       0       0       0       0         Hypoxia       subjects affected / exposed       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	occurrences (all)	14	13	0
subjects affected / exposed       6 / 39 (15.38%)       5 / 35 (14.29%)       1 / 2 (50.00%)         occurrences (all)       8       6       1         Dyspnoea       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         occurrences (all)       5       5       0         Epistaxis       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0       0       0       0       0         Hypoxia       subjects affected / exposed       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	Dysphonia			
Dyspnoea       5/39 (12.82%)       4/35 (11.43%)       0/2 (0.00%)         occurrences (all)       5       5       0         Epistaxis       subjects affected / exposed       0/39 (0.00%)       0/35 (0.00%)       0/2 (0.00%)         occurrences (all)       0       0       0       0       0         Hypoxia       subjects affected / exposed       0/39 (0.00%)       1/35 (2.86%)       0/2 (0.00%)         occurrences (all)       0       2       0	subjects affected / exposed	6 / 39 (15.38%)	5 / 35 (14.29%)	1 / 2 (50.00%)
subjects affected / exposed       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         occurrences (all)       5       5       0         Epistaxis       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Hypoxia       subjects affected / exposed       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	occurrences (all)	8	6	1
subjects affected / exposed       5 / 39 (12.82%)       4 / 35 (11.43%)       0 / 2 (0.00%)         occurrences (all)       5       5       0         Epistaxis       subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         Hypoxia       subjects affected / exposed       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	Dyspnoea			
occurrences (all)550Epistaxis subjects affected / exposed occurrences (all)0 / 39 (0.00%) 00 / 35 (0.00%) 00 / 2 (0.00%) 0Hypoxia subjects affected / exposed occurrences (all)0 / 39 (0.00%) 01 / 35 (2.86%) 20 / 2 (0.00%) 0		5 / 39 (12.82%)	4 / 35 (11.43%)	0 / 2 (0.00%)
subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0       0       0         Hypoxia       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	occurrences (all)		5	0
subjects affected / exposed       0 / 39 (0.00%)       0 / 35 (0.00%)       0 / 2 (0.00%)         occurrences (all)       0       0       0         Hypoxia       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	Epistaxis			
occurrences (all)       0       0       0         Hypoxia       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0		0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
subjects affected / exposed       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	occurrences (all)			
subjects affected / exposed       0 / 39 (0.00%)       1 / 35 (2.86%)       0 / 2 (0.00%)         occurrences (all)       0       2       0	Hypoxia			
occurrences (all) 0 2 0		0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
Nasal congestion				
	Nasal congestion			

subjects affected / exposed	5 / 39 (12.82%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	6	7	0
Oropharyngeal pain			
subjects affected / exposed	3 / 39 (7.69%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
Pleural effusion			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed			
occurrences (all)	7 / 39 (17.95%)	10 / 35 (28.57%)	1 / 2 (50.00%)
	8	12	1

Lymphopenia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Thrombocytosis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	3 / 39 (7.69%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Dysaesthesia			
subjects affected / exposed	5 / 39 (12.82%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	5	4	0
Dysarthria			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	20 / 39 (51.28%)	9 / 35 (25.71%)	1 / 2 (50.00%)
occurrences (all)	27	12	1
Headache			
subjects affected / exposed	4 / 39 (10.26%)	5 / 35 (14.29%)	0 / 2 (0.00%)
occurrences (all)	6	5	0
Hemianopia homonymous			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Monoparesis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Peripheral sensory neuropathy			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	6 / 39 (15.38%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	7	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Eye pruritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
	0		
Eyelid oedema subjects affected / exposed		0	0
Eyelid oedema	0 0 / 39 (0.00%) 0		
Eyelid oedema subjects affected / exposed occurrences (all)	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
Eyelid oedema subjects affected / exposed occurrences (all) Lacrimation increased	0 / 39 (0.00%) 0	0 0 / 35 (0.00%) 0	0 0 / 2 (0.00%) 0
Eyelid oedema subjects affected / exposed occurrences (all) Lacrimation increased subjects affected / exposed	0 / 39 (0.00%) 0 0 / 39 (0.00%)	0 0 / 35 (0.00%) 0 0 / 35 (0.00%)	0 0 / 2 (0.00%) 0 0 / 2 (0.00%)
Eyelid oedema subjects affected / exposed occurrences (all) Lacrimation increased	0 / 39 (0.00%) 0	0 0 / 35 (0.00%) 0	0 0 / 2 (0.00%) 0
Eyelid oedema subjects affected / exposed occurrences (all) Lacrimation increased subjects affected / exposed	0 / 39 (0.00%) 0 0 / 39 (0.00%)	0 0 / 35 (0.00%) 0 0 / 35 (0.00%)	0 0 / 2 (0.00%) 0 0 / 2 (0.00%)
Eyelid oedema subjects affected / exposed occurrences (all) Lacrimation increased subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0 0 / 39 (0.00%)	0 0 / 35 (0.00%) 0 0 / 35 (0.00%)	0 0 / 2 (0.00%) 0 0 / 2 (0.00%)
Eyelid oedema subjects affected / exposed occurrences (all) Lacrimation increased subjects affected / exposed occurrences (all) Orbital myositis	0 / 39 (0.00%) 0 0 / 39 (0.00%) 0	0 0 / 35 (0.00%) 0 0 / 35 (0.00%) 0	0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Vision blurred subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	2 / 39 (5.13%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	8 / 39 (20.51%)	11 / 35 (31.43%)	0 / 2 (0.00%)
occurrences (all)	17	24	0
Abdominal pain upper			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atrophic glossitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
--	----------------------	----------------------	---------------------
Colitis subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed occurrences (all)	5 / 39 (12.82%) 8	7 / 35 (20.00%) 8	1 / 2 (50.00%) 1
Diarrhoea			
subjects affected / exposed	24 / 39 (61.54%)	19 / 35 (54.29%)	0 / 2 (0.00%)
occurrences (all)	53	32	0
Dry mouth			
subjects affected / exposed	4 / 39 (10.26%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	4	4	0
Dyspepsia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Dysphagia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Haematochezia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)

occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	5	1	0
Nausea			
subjects affected / exposed	11 / 39 (28.21%)	11 / 35 (31.43%)	0 / 2 (0.00%)
occurrences (all)	13	17	0
Odynophagia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1		0
	L	1	0
Salivary hypersecretion			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	4 / 39 (10.26%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	4	2	0
Toothache			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	9 / 39 (23.08%)	8 / 35 (22.86%)	1 / 2 (50.00%)
occurrences (all)	11	13	1
	11	15	I
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Anuria			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
	-	-	-
Dysuria			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Leukocyturia			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nephritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Delleliuie			
Pollakiuria subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Polyuria subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0 / 39 (0.00%)	0 / 55 (0.00 %)	0 / 2 (0.00 %)
	Ū	Ū	0
Proteinuria subjects affected / exposed			
occurrences (all)	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
	1	0	0
Renal failure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholestasis subjects affected / exposed			
occurrences (all)	0 / 39 (0.00%) 0	0 / 35 (0.00%) 0	0 / 2 (0.00%) 0
	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin subjects affected / exposed	7 / 39 (17.95%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	7	- , , , , , , , , , , , , , , , , , , ,	0
		5	J
Erythema subjects affected / exposed			
occurrences (all)	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
	0	1	0
Hair colour changes			
subjects affected / exposed	3 / 39 (7.69%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Hyperhidrosis			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)

occurrences (all)	2	1	0
Hypohidrosis			
subjects affected / exposed	3 / 39 (7.69%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Palmar-plantar erythrodysaesthaesia syndrome			
subjects affected / exposed	13 / 39 (33.33%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	18	7	0
Papule			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritis			
subjects affected / exposed	9 / 39 (23.08%)	8 / 35 (22.86%)	0 / 2 (0.00%)
occurrences (all)	13	10	0
Rash			
subjects affected / exposed	1 / 39 (2.56%)	5 / 35 (14.29%)	1 / 2 (50.00%)
occurrences (all)	1	6	1
Rash erythematous			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	6 / 39 (15.38%)	7 / 35 (20.00%)	0 / 2 (0.00%)
occurrences (all)	6	10	0
Rash pruritic			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Skin lesion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	10 / 39 (25.64%)	13 / 35 (37.14%)	0 / 2 (0.00%)
occurrences (all)	22	23	0
Arthritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	3 / 39 (7.69%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	7	4	0
Dactylitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain subjects affected / exposed			
occurrences (all)	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
	0	0	0
Immune-mediated arthritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musslo spasme			
Muscle spasms subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	1 1 1	1 / 55 (2.80%)	0 / 2 (0.00%)
		-	, , , , , , , , , , , , , , , , , , ,
Muscular weakness			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

I			
Musculoskeletal pain			
subjects affected / exposed	2 / 39 (5.13%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	4	4	0
Myalgia			
subjects affected / exposed	7 / 39 (17.95%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	10	6	0
Neck pain			
subjects affected / exposed	2 / 39 (5.13%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Pain in extremity			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Spondylitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders Hyperthyroidism			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
	Ũ	-	Ű
Hypothyroidism			
subjects affected / exposed	1 / 39 (2.56%)	1 / 35 (2.86%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	8 / 39 (20.51%)	9 / 35 (25.71%)	0 / 2 (0.00%)
occurrences (all)	16	12	0
Dehydration			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0 / 39 (0.00%)	0 / 33 (0.00%)	0 / 2 (0.00%)
	, , , , , , , , , , , , , , , , , , ,	, , , , , , , , , , , , , , , , , , ,	Ŭ I
Hypercholesterolaemia			

subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	1 / 2 (50.00%)
occurrences (all)	1	2	2
Hyperkalaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 39 (2.56%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Hypocalcaemia			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Hypoglycaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	3 / 39 (7.69%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Hypomagnasaemia			
subjects affected / exposed	1 / 39 (2.56%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	1	5	0
Polydipsia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin B6 deficiency			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			

subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	0 / 35 (0.00%) 0	0 / 2 (0.00%) 0
Hyponatraemia subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia subjects affected / exposed	2 / 39 (5.13%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	8 / 39 (20.51%)	3 / 35 (8.57%)	0 / 2 (0.00%)
occurrences (all)	8	3	0
Influenza			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lip infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
l	l		

Oropharyngeal candidiasis subjects affected / exposed			_ / _ /
	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 35 (2.86%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Respiratory tract infection			
subjects affected / exposed	1 / 39 (2.56%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0 / 2 (0.00 /0)
Tooth abscess subjects affected / exposed			
	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	2 / 35 (5.71%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	2 / 39 (5.13%)	4 / 35 (11.43%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
Varicella			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular device infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 35 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Breast	Lung	Pancreatic
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	17 / 17 (100.00%)
/ascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	1	1	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Haemangioma subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0 0	0 / 3 (0.00 %)	1 (3.86%)
Skin papilloma subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Tumour flare subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	1 / 17 (5.88%) 1
Tumour pain subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	1 / 3 (33.33%) 6	4 / 17 (23.53%) 4
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	1 / 17 (5.88%) 1
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 17 (0.00%) 0
General disorders and administration site conditions Asthenia			
subjects affected / exposed	1 / 2 (50.00%)	3 / 3 (100.00%)	3 / 17 (17.65%)
occurrences (all)	1	5	4
Catheter site pain subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Chest pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 3 (33.33%) 1	1 / 17 (5.88%) 1
Chills subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 2	2 / 3 (66.67%) 3	2 / 17 (11.76%) 2
Cyst subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 3 (0.00%) 0	0 / 17 (0.00%) 0
Fatigue			

subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	6 / 17 (35.29%)
occurrences (all)	1	1	7
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gravitational oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Mucosal dryness			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)
occurrences (all)	0	0	3
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 2 (100.00%)	3 / 3 (100.00%)	7 / 17 (41.18%)
occurrences (all)	2	12	8
Swelling			

0.00%)     0 / 3 (0.       0.00%)     0 / 3 (0.       0.00%)     0 / 3 (0.       0.00%)     0 / 3 (0.       0.00%)     0 / 3 (0.       0.00%)     1 / 3 (33       0.00%)     1 / 3 (33       0.00%)     0 / 3 (0.       0.00%)     0 / 3 (0.       0.00%)     1 / 3 (33       0.00%)     1 / 3 (33	.00%) 0 / 17 ( .00%) 0 / 17 ( .00%) 0 / 17 ( .3.33%) 1 / 17 ( .3.33%) 0 / 17 ( .00%) 0 / 17 ( .00%) 0 / 17 (	0.00%) 0.00%) 0.00%) 0.00%) 0.00%) 0.00%)
) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	.00%) 0 / 17 ( .00%) 1 / 17 ( .3.33%) 1 / 17 ( .3.33%) 0 / 17 ( .00%) 0 / 17 ( .00%) 0 / 17 (	0.00%) ) 5.88%) L 0.00%) ) 0.00%)
) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	.00%) 0 / 17 ( .00%) 1 / 17 ( .3.33%) 1 / 17 ( .3.33%) 0 / 17 ( .00%) 0 / 17 ( .00%) 0 / 17 (	0.00%) ) 5.88%) L 0.00%) ) 0.00%)
) 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	.00%) 0 / 17 ( .00%) 1 / 17 ( .3.33%) 1 / 17 ( .3.33%) 0 / 17 ( .00%) 0 / 17 ( .00%) 0 / 17 (	0.00%) ) 5.88%) L 0.00%) ) 0.00%)
0.00%)     0 / 3 (0.       0     0       0.00%)     1 / 3 (33       0.00%)     1 / 3 (33       0.00%)     1 / 3 (33       0     1       0.00%)     0 / 3 (0.       0     0	.00%) 0 / 17 ( .00%) 1 / 17 ( .3.33%) 1 / 17 ( .3.33%) 0 / 17 ( .00%) 0 / 17 ( .00%) 0 / 17 (	0.00%) 5.88%) 0.00%) 0.00%) 0.00%)
0 0.00%) 1 / 3 (33 0.00%) 1 / 3 (33 1 0.00%) 0 / 3 (0. 0 0 0	3.33%) 1 / 17 ( 3.33%) 0 / 17 ( .00%) 0 / 17 ( 3.33%) 0 / 17 (	5.88%) L 0.00%) ) 0.00%)
0 0.00%) 1 / 3 (33 0.00%) 1 / 3 (33 1 0.00%) 0 / 3 (0. 0 0 0	3.33%) 1 / 17 ( 3.33%) 0 / 17 ( .00%) 0 / 17 ( 3.33%) 0 / 17 (	5.88%) L 0.00%) ) 0.00%)
0.00%) 1 / 3 (33 ) 2 ).00%) 1 / 3 (33 ) 1 ).00%) 0 / 3 (0. ) 0	3.33%) 1 / 17 ( 1 3.33%) 0 / 17 ( .00%) 0 / 17 ( 3.33%) 0 / 17 (	5.88%) L 0.00%) ) 0.00%)
) 2 ).00%) 1 / 3 (33 ) 1 ).00%) 0 / 3 (0. ) 0	3.33%) 0 / 17 ( .00%) 0 / 17 ( .3.33%) 0 / 17 (	L 0.00%) ) 0.00%) 0.00%)
) 2 ).00%) 1 / 3 (33 ) 1 ).00%) 0 / 3 (0. ) 0	3.33%) 0 / 17 ( .00%) 0 / 17 ( .3.33%) 0 / 17 (	L 0.00%) ) 0.00%) 0.00%)
) 2 ).00%) 1 / 3 (33 ) 1 ).00%) 0 / 3 (0. ) 0	3.33%) 0 / 17 ( .00%) 0 / 17 ( .3.33%) 0 / 17 (	L 0.00%) ) 0.00%) )
0.00%) 1 / 3 (33 ) 1 ).00%) 0 / 3 (0. ) 0	3.33%) 0 / 17 ( .00%) 0 / 17 ( .3.33%) 0 / 17 (	0.00%) ) 0.00%) ) 0.00%)
) 1 ).00%) 0 / 3 (0. ) 0	.00%) 0 / 17 ( .033%) 0 / 17 (	) 0.00%) ) 0.00%)
) 1 ).00%) 0 / 3 (0. ) 0	.00%) 0 / 17 ( .033%) 0 / 17 (	) 0.00%) ) 0.00%)
) 1 ).00%) 0 / 3 (0. ) 0	.00%) 0 / 17 ( .033%) 0 / 17 (	) 0.00%) ) 0.00%)
0 0	3.33%) 0 / 17 (	) 0.00%)
0 0	3.33%) 0 / 17 (	0.00%)
0 0	3.33%) 0 / 17 (	0.00%)
0.00%) 1 / 3 (33		_
0.00%) 1 / 3 (33		_
	C	)
1	I	
0.00%) 2 / 3 (66	5.67%) 0/17(	0.00%)
2	c	)
0.00%) 1 / 3 (33	3.33%) 0 / 17 (	0.00%)
		-
0.00%) 0/3(0.	.00%) 0 / 17 (	0.00%)
		-
I	.00%) 0 / 17 (	0.00%)
0.00%) 0/3(0.	· · · ·	,
C	0.00%) 0 / 3 (0. 0 0	0.00%) 0 / 3 (0.00%) 0 / 17 ( 0 0 0

Penile rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Incision site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	3 / 3 (100.00%)	7 / 17 (41.18%)
occurrences (all)	0	3	13
Joint injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Aspartate aminotransferase			
increased subjects affected / exposed			
	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Blood fibrinogen decreased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase			
increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Serum ferritin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
	Ĭ	Ť	Ť
Atrial flutter			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
Tachycardia subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0 / 2 (0.00 %)	1 / 5 (55.55%)	0 0 0
		1	U
Ventricular fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			
disorders			
Aphonia subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
		U	U
Asthma			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
1	1	I	ı I

occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)
occurrences (all)	1	0	5
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	2 / 17 (11.76%)
occurrences (all)	0	2	2
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
I have a fee			
Hypoxia subjects affected / exposed			
	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
occurrences (all)			
	0	1	2
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)			
	0	0	0
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Sputum discoloured			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	3 / 17 (17.65%)
occurrences (all)	1	1	3
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
	0	0	2
Thrombocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	1	0	3

Dysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	8 / 17 (47.06%)
occurrences (all)	0	2	8
Headache			
subjects affected / exposed	1 / 2 (50.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
occurrences (all)	1	4	3
Hemianopia homonymous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Monoparesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Paraesthesia subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye pruritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Orbital myositis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Periorbital swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Retinal artery occlusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Abdominal pain subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       5 / 17 (29.41%) 6         Abdominal pain subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       1 / 17 (5.88%) 0         Abdominal tenderness subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       5 / 17 (29.41%) 6         Diarrhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (0.00%) 1       3 / 10 / 17 (58.82%) 10         Diarrhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       3 / 17 (17.65%) 3         Dry mouth subjects affected / exposed occurrences (all)	Abdominal distension	I	l	
occurrences (all)       0       1       0         Abdominal pain subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       5 / 17 (29.41%) 6         Abdominal pain upper subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       1 / 17 (5.88%) 0         Abdominal tenderness subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 1       0 / 17 (0.00%) 0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (30.00%) 0       0 / 17 (0.00%) 0         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1 / 3 (33.33%)       5 / 17 (29.41%) 6         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%) 3       2 / 3 (66.67%) 1 / 12       10 / 17 (58.82%) 3         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       3 / 17 (17.65%) 3		0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       5 / 17 (29.41%) 6         Abdominal pain upper subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       1 / 17 (5.88%) 1         Abdominal tenderness subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       5 / 17 (29.41%) 6         Diarnhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 10 / 17 (58.82%) 2 / 2 (100.00%) 3 / 4       10 / 17 (58.82%) 12         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 3 / 17 (17.65%) 3       3 / 17 (17.65%) 3	occurrences (all)		1	
subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       5 / 17 (29.41%) 6         Abdominal pain upper subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       1 / 17 (5.88%) 1         Abdominal tenderness subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       5 / 17 (29.41%) 6         Diarnhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 10 / 17 (58.82%) 2 / 2 (100.00%) 3 / 4       10 / 17 (58.82%) 12         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 3 / 17 (17.65%) 3       3 / 17 (17.65%) 3				
occurrences (all)       0       0       0       6         Abdominal pain upper subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         Abdominal tenderness subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       5 / 17 (29.41%)         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%)       2 / 3 (66.67%)       10 / 17 (58.82%)         Diarrhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)	•			
Abdominal pain upper subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       1 / 17 (5.88%) 1         Abdominal tenderness subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%) 0       2 / 3 (66.67%) 10 / 17 (58.82%) 12       3 / 17 (17.65%) 3         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       3 / 17 (17.65%) 3				
subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       1 / 17 (5.88%) 1         Abdominal tenderness subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1 / 3 (33.33%)       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 1       0 / 17 (0.00%) 0         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1       5 / 17 (29.41%) 6         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%) 1       2 / 3 (66.67%) 1       10 / 17 (58.82%) 12         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 3       3 / 17 (17.65%) 3		0	0	6
occurrences (all)001Abdominal tenderness subjects affected / exposed occurrences (all)0 / 2 (0.00%) 00 / 3 (0.00%) 00 / 17 (0.00%) 0Anal fissure subjects affected / exposed occurrences (all)0 / 2 (0.00%) 01 / 3 (33.33%) 00 / 17 (0.00%) 0Ascites subjects affected / exposed occurrences (all)0 / 2 (0.00%) 01 / 3 (33.33%) 00 / 17 (0.00%) 0Ascites subjects affected / exposed occurrences (all)0 / 2 (0.00%) 01 / 3 (33.33%) 00 / 17 (0.00%) 0Atrophic glossitis subjects affected / exposed occurrences (all)0 / 2 (0.00%) 00 / 3 (0.00%) 00 / 17 (0.00%) 0Colitis subjects affected / exposed occurrences (all)0 / 2 (0.00%) 00 / 3 (0.00%) 00 / 17 (0.00%) 0Colitis subjects affected / exposed occurrences (all)0 / 2 (0.00%) 01 / 3 (33.33%) 05 / 17 (29.41%) 1Diarrhoea subjects affected / exposed occurrences (all)2 / 2 (100.00%) 32 / 3 (66.67%) 110 / 17 (58.82%) 12Dry mouth subjects affected / exposed occurrences (all)0 / 2 (0.00%) 30 / 3 (0.00%) 3 / 17 (17.65%)Dry mouth subjects affected / exposed occurrences (all)0 / 2 (0.00%) 30 / 3 (0.00%) 3 / 17 (17.65%)	Abdominal pain upper			
Abdominal tenderness subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Anal fissure subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (33.33\%)$ $0 / 17 (0.00\%)$ Ascites subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (33.33\%)$ $0 / 17 (0.00\%)$ Ascites subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (33.33\%)$ $0 / 17 (0.00\%)$ Atrophic glossitis subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Colitis subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Constipation subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (33.33\%)$ $5 / 17 (29.41\%)$ Diarrhoea subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (30.33\%)$ $5 / 17 (29.41\%)$ Diarrhoea subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (30.33\%)$ $5 / 17 (29.41\%)$ Diarrhoea subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $3 / 17 (17.65\%)$ Dry mouth subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $3 / 17 (17.65\%)$ Dry mouth subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1 / 3 (33.33%)       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1 / 3 (33.33%)       0 / 17 (0.00%) 0         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1 / 3 (33.33%)       5 / 17 (29.41%) 6         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%) 3       2 / 3 (66.67%) 4       10 / 17 (58.82%) 12         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 3       3 / 17 (17.65%) 3	occurrences (all)	0	0	1
occurrences (all)       0       0       0         Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       5 / 17 (29.41%)         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%)       1 / 3 (30.33%)       10 / 17 (58.82%)         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)         Dryspepsia subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)	Abdominal tenderness			
Anal fissure subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1 / 3 (33.33%)       0 / 17 (0.00%) 0         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 0       0 / 17 (0.00%) 0         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1       5 / 17 (29.41%) 6         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%) 3       2 / 3 (66.67%) 1       10 / 17 (58.82%) 12         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 3       3 / 17 (17.65%) 3         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%)       3 / 17 (17.65%) 3	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       5 / 17 (29.41%)         Diarrhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (66.67%)       10 / 17 (58.82%)         Diarrhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       2 / 3 (66.67%)       10 / 17 (58.82%)         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)         Dyspepsia subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)	occurrences (all)	0	0	0
subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       5 / 17 (29.41%)         Diarrhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (66.67%)       10 / 17 (58.82%)         Diarrhoea subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       2 / 3 (66.67%)       10 / 17 (58.82%)         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)         Dyspepsia subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)				
occurrences (all)     0     1     0       Ascites     subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     0 / 17 (0.00%)       occurrences (all)     0     1     0     0     1     0       Atrophic glossitis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Colitis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Constipation     subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6     10     12       Diarrhoea     subjects affected / exposed     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     0 / 2 (0.00%)     0 / 17 (0.00%)			1 / 2 / 22 220/ \	0 ( 17 (0 000) )
Ascites subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         Atrophic glossitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Constipation subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       1 / 3 (33.33%)       5 / 17 (29.41%)         Diarrhoea subjects affected / exposed occurrences (all)       2 / 2 (100.00%)       2 / 3 (66.67%)       10 / 17 (58.82%)         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)         Dry mouth subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)         Dyspepsia subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)	-			
subjects affected / exposed       0 / 2 (0.00%)       1 / 3 (33.33%)       0 / 17 (0.00%)         occurrences (all)       0       1       0       0         Atrophic glossitis subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Colitis subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Constipation subjects affected / exposed       0 / 2 (0.00%)       1 / 3 (33.33%)       5 / 17 (29.41%)         occurrences (all)       0       1       6       10         Diarrhoea subjects affected / exposed       2 / 2 (100.00%)       2 / 3 (66.67%)       10 / 17 (58.82%)         occurrences (all)       3       4       12         Dry mouth subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)         0       0       0       3       0       3		0	1	0
occurrences (all)     0     1     0       Atrophic glossitis subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Colitis subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Constipation subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6       Diarrhoea subjects affected / exposed     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     10 / 17 (0.00%)	Ascites			
Atrophic glossitis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Colitis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Constipation     subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6     6       Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     12       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     0 / 17 (0.00%)     3 / 17 (17.00%)	subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Colitis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       Constipation     subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6     6       Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     3     12       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     0     10 / 17 (0.00%)	occurrences (all)	0	1	0
occurrences (all)     0     0     0       Colitis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Constipation     subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6     6       Diarrhoea     subjects affected / exposed     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     0     3       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3     3     3	Atrophic glossitis			
Colitis     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Constipation     subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     3 (33.33%)     5 / 17 (29.41%)       Diarrhoea     0 / 2 (0.00%)     1     6       Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0       Constipation     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6       Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     3     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       Dry mouth     0     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       byspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	0	0	0
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0       Constipation     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6       Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     3     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       Dry mouth     0     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       byspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	Colitis			
occurrences (all)     0     0     0       Constipation     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6       Diarrhoea     2 / 2 (100.00%)     1     6       subjects affected / exposed     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)		0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
Constipation subjects affected / exposed occurrences (all)0 / 2 (0.00%) 01 / 3 (33.33%) 15 / 17 (29.41%) 6Diarrhoea subjects affected / exposed occurrences (all)2 / 2 (100.00%) 32 / 3 (66.67%) 410 / 17 (58.82%) 12Dry mouth subjects affected / exposed occurrences (all)0 / 2 (0.00%) 00 / 3 (0.00%) 33 / 17 (17.65%) 3Dyspepsia subjects affected / exposed occurrences (all)0 / 2 (0.00%) 00 / 3 (0.00%) 03 / 17 (17.65%) 3	occurrences (all)			
subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     5 / 17 (29.41%)       occurrences (all)     0     1     6       Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3				
occurrences (all)     0     1     6       Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     0     3     0 / 3 (0.00%)     3 / 17 (17.65%)       Dry mouth     0     0     0     0     3     3     0 / 17 (0.00%)       Dyspepsia     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)				
Diarrhoea     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     3     4     12       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3       Dyspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)			1 / 3 (33.33%)	5 / 17 (29.41%)
subjects affected / exposed     2 / 2 (100.00%)     2 / 3 (66.67%)     10 / 17 (58.82%)       occurrences (all)     3     4     12       Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       Dyspepsia     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	0	1	6
occurrences (all)     3     4     12       Dry mouth     3     4     12       occurrences (all)     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3       Dyspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	Diarrhoea			
Dry mouth     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3       Dyspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	subjects affected / exposed	2 / 2 (100.00%)	2 / 3 (66.67%)	10 / 17 (58.82%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3       Dyspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	3	4	12
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     3 / 17 (17.65%)       occurrences (all)     0     0     3       Dyspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	Dry mouth			
occurrences (all)     0     0     3       Dyspepsia     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	•	0 / 2 (0.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)
subjects affected / exposed   0 / 2 (0.00%)   0 / 3 (0.00%)   0 / 17 (0.00%)	occurrences (all)			
subjects affected / exposed   0 / 2 (0.00%)   0 / 3 (0.00%)   0 / 17 (0.00%)	Ducponcia			
		0 / 2 (0 00%)	0 / 3 (0 00%)	0 / 17 (0 00%)
			U U	U

Dycobagia		l	I
Dysphagia subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Enteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Glossitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2 / 17 (11.7070)
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
			_
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	5 / 17 (29.41%)
occurrences (all)	1	3	7
Odynophagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Coliner hundred with			
Salivary hypersecretion subjects affected / exposed		0 / 2 /0 000/ )	
	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
			1

Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0/3(0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	7 / 17 (41.18%)
occurrences (all)	0	3	10
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0/3(0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Anuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Nephritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0/3(0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Polyuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)

Hepatobiliary disorders Cholestasis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Portal vein thrombosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         occurrences (all)       0       0       0       1         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed       1 / 2 (50.00%)       1 / 3 (33.33%)       2 / 17 (11.76%)         occurrences (all)       1       1       2         Erythema subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Hair colour changes subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0       1         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         occurrences (all)       0       0       0       1         Hypohidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 17 (0.00%)       0 / 17 (0.00%)	occurrences (all)	0	0	0
Cholestasis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Portal vein thrombosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         occurrences (all)       0       0       0       1         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed       1 / 2 (50.00%)       1 / 3 (33.33%)       2 / 17 (11.76%)         occurrences (all)       1       1       2         Erythema subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Hair colour changes subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Hyperhidrosis subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         occurrences (all)       0       0       1       1         Hypohidrosis subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (0.00%)         occurrences (all)       0       0       0       1	Hepatohiliary disorders			
subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Portal vein thrombosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         O / 2 (0.00%)       0       0       0       1         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed       1 / 2 (50.00%)       1 / 3 (33.33%)       2 / 17 (11.76%)         occurrences (all)       1       1       2         Erythema subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Hair colour changes subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Hyperhidrosis subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         occurrences (all)       0       0       1       1         Hypohidrosis subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0				
occurrences (all)000Portal vein thrombosis subjects affected / exposed occurrences (all)0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed1 / 2 (50.00%)1 / 3 (33.33%)2 / 17 (11.76%)Occurrences (all)112Erythema subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Hair colour changes subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)Palmar-plantar erythrodysaesthaesia		0 / 2 (0.00%)	0/3(0.00%)	0 / 17 (0.00%)
subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)       1 / 2 (50.00%)       1 / 3 (33.33%)       2 / 17 (11.76%)         Erythema subjects affected / exposed occurrences (all)       1       1       2         Erythema subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Attir colour changes subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Occurrences (all)       0       0       0       0       0         Hair colour changes subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Occurrences (all)       0       0       0       0       0         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         O / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)       0       0         Hyperhidrosis subjects affected / exposed occurrences (all)       0       0       0       0         Palmar-plantar erythrodysaesthaesia       0 / 2 (0.00%) <td< td=""><td>occurrences (all)</td><td></td><td></td><td></td></td<>	occurrences (all)			
occurrences (all)       0       0       0       1         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)       1 / 2 (50.00%)       1 / 3 (33.33%)       2 / 17 (11.76%)         Currences (all)       1       1       2         Erythema subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Hair colour changes subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0       0       0       0         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         occurrences (all)       0       0       1       1         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hypohidrosis subjects affected / exposed occurrences (all)       0       0       0       0         Palmar-plantar erythrodysaesthaesia       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)       0	Portal vein thrombosis			
occurrences (all)001Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed1 / 2 (50.00%)1 / 3 (33.33%)2 / 17 (11.76%)Occurrences (all)1112Erythema subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)Occurrences (all)0000Hair colour changes subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)Occurrences (all)0000Hair colour changes subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)Occurrences (all)0011Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)Occurrences (all)0011Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)Occurrences (all)0000Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)Occurrences (all)0000Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 17 (0.00%)0Occurrences (all)0000Palmar-plantar erythrodysaesthaesia0000	subjects affected / exposed	0 / 2 (0.00%)	0/3(0.00%)	1 / 17 (5.88%)
Dry skin subjects affected / exposed occurrences (all)       1 / 2 (50.00%)       1 / 3 (33.33%)       2 / 17 (11.76%)         Erythema subjects affected / exposed occurrences (all)       0       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hair colour changes subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hair colour changes subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         OCurrences (all)       0       0       0       1         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hypohidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         O / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)       0       0         Hypohidrosis subjects affected / exposed occurrences (all)       0       0       0       0         Palmar-plantar erythrodysaesthaesia       0       0       0       0       0	occurrences (all)			
Dry skin subjects affected / exposed occurrences (all)       1 / 2 (50.00%)       1 / 3 (33.33%)       2 / 17 (11.76%)         Erythema subjects affected / exposed occurrences (all)       0       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hair colour changes subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hair colour changes subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       1 / 17 (5.88%)         OCurrences (all)       0       0       0       1         Hyperhidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         Hypohidrosis subjects affected / exposed occurrences (all)       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         O / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)       0       0         Hypohidrosis subjects affected / exposed occurrences (all)       0       0       0       0         Palmar-plantar erythrodysaesthaesia       0       0       0       0       0	Skin and subcutaneous tissue disorders			
subjects affected / exposed     1 / 2 (50.00%)     1 / 3 (33.33%)     2 / 17 (11.76%)       occurrences (all)     1     1     2       Erythema     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Hair colour changes     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Hyperhidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       occurrences (all)     0     0     1     1       Hypohidrosis     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     1       Hypohidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Palmar-plantar erythrodysaesthaesia     0     0     0     0     0 <td></td> <td></td> <td></td> <td></td>				
Erythema subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Hair colour changes subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.00%)occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Palmar-plantar erythrodysaesthaesia0000		1 / 2 (50.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Hair colour changes     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Hyperhidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       occurrences (all)     0     0     1     1       Hypohidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     1       Hypohidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Palmar-plantar erythrodysaesthaesia     0     0     0     0	occurrences (all)	1	1	
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Hair colour changes     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Hyperhidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       occurrences (all)     0     0     1     1       Hypohidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     1       Hypohidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Palmar-plantar erythrodysaesthaesia     0     0     0     0	Frythema			
occurrences (all)000Hair colour changes subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Palmar-plantar erythrodysaesthaesia0000	,	0 / 2 (0.00%)	0/3(0.00%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Hyperhidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       occurrences (all)     0     0     0     1       Hypohidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Palmar-plantar erythrodysaesthaesia     0     0     0     0	occurrences (all)			
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Hyperhidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       occurrences (all)     0     0     0     1       Hypohidrosis     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Palmar-plantar erythrodysaesthaesia     0     0     0     0				
occurrences (all)000Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)Occurrences (all)0000Occurrences (all)0000Occurrences (all)0000Occurrences (all)0000Occurrences (all)0000Orange (all)0000Orange (all)0000				
Hyperhidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)1 / 17 (5.88%)occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000occurrences (all)0000palmar-plantar erythrodysaesthaesia0000		0 / 2 (0.00%)	0/3(0.00%)	0 / 1 / (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       occurrences (all)     0     0     1       Hypohidrosis     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0       Palmar-plantar erythrodysaesthaesia     0     0     0	occurrences (all)	0	0	0
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     1 / 17 (5.88%)       occurrences (all)     0     0     1       Hypohidrosis     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0       Palmar-plantar erythrodysaesthaesia     0     0     0	Hyperhidrosis			
occurrences (all)001Hypohidrosis subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Palmar-plantar erythrodysaesthaesia000		0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0	occurrences (all)			1
subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)         occurrences (all)       0	Hypohidrosis			
occurrences (all)00Palmar-plantar erythrodysaesthaesia0		0 / 2 (0 00%)	0 / 3 (0 00%)	0 / 17 (0.00%)
Palmar-plantar erythrodysaesthaesia	occurrences (all)			
		0	0	0
syndrome       0 / 2 (0.00%)       0 / 3 (0.00%)       4 / 17 (23.53%)	-	0 / 2 (0 00%)	0 / 3 (0 00%)	4 / 17 (23 53%)
occurrences (all)       0       0       4				
Papule       1 / 2 (50.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)	-			0 / 17 /0 000/
		1 / 2 (50.00%)	0/3(0.00%)	0 / 1 / (0.00%)
occurrences (all) 1 0 0	occurrences (all)	1	0	0
Pruritis	Pruritis			
subjects affected / exposed       2 / 2 (100.00%)       0 / 3 (0.00%)       6 / 17 (35.29%)	subjects affected / exposed	2 / 2 (100.00%)	0/3(0.00%)	6 / 17 (35.29%)
occurrences (all) 3 0 7	occurrences (all)	3	0	7
Rash	Rash			
subjects affected / exposed       1 / 2 (50.00%)       0 / 3 (0.00%)       3 / 17 (17.65%)		1 / 2 (50.00%)	0 / 3 (0.00%)	3 / 17 (17.65%)

occurrences (all)	1	0	4
Rash erythematous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	4 / 17 (23.53%)
occurrences (all)	0	0	5
Rash pruritic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	4 / 17 (23.53%)
occurrences (all)	0	1	4
Skin lesion			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Solar dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urticaria subjects affected / exposed			0 ( 17 (0 000()
	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Arthritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	3	1
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
occurrences (all)	1	2	2
Dactylitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0 / 2 (0.00 /0)	0	0
	0	U	0

Flank pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Immune-mediated arthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
occurrences (all)	0	2	1
Spondylitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0

<b></b>			
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)			
	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	2 / 3 (66.67%)	5 / 17 (29.41%)
occurrences (all)	1	3	5
	-	-	
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
	0 / 2 (0.00 %)	0 / 5 (0.00 %)	0 / 1 / (0.00 %)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
	Ŭ	0	Ū
Hypercholesterolaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
	0 / 2 (0.00%)	0/3(0.00%)	0 / 1 / (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
	U	0	U
Hyperkalaemia			
subjects affected / exposed			
	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
		U	U
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 /0 000/ )	1 / 2 / 22 220/ \	0 / 17 /0 000/)
	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
I	I <sup>-</sup>	•	· · · ·

occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Hypomagnasaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Polydipsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitamin B6 deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 17 (5.88%)
occurrences (all)	0	1	1
Humanatraamia			
Hyponatraemia subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)			
	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			

subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	2 / 17 (11.76%)
occurrences (all)	0	3	2
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
occurrences (all)	0	1	0
Lip infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	2 / 17 (11.76%)
occurrences (all)	0	1	2
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Sinusitis			

Clinical trial results 2015-003771-30 version 1

occurrences (all)       0       0       0         Skin candida subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Tooth abscess subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Upper respiratory tract infection subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       1 / 3 (33.33%) 1 / 3 (33.33%)       0 / 17 (0.00%) 0         Urinary tract infection subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       2 / 3 (66.67%) 2 / 3 (66.67%)       1 / 17 (5.88%) 2 / 3 (0.00%)         Varicella subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Vascular device infection subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%) 0         Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)       0 / 2 (0.00%) 0       0 / 3 (0.00%) 0       0 / 17 (0.00%)	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Tooth abscess subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Upper respiratory tract infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (33.33\%)$ $0 / 17 (0.00\%)$ Urinary tract infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $2 / 3 (66.67\%)$ $1 / 17 (5.88\%)$ Varicella subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Varicella subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Vascular device infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Vulvovaginal mycotic infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$	occurrences (all)	0	0	0
subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Tooth abscess subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Upper respiratory tract infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $1 / 3 (33.33\%)$ $0 / 17 (0.00\%)$ Urinary tract infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $2 / 3 (66.67\%)$ $1 / 17 (5.88\%)$ Varicella subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Varicella subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Vascular device infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$ Vulvovaginal mycotic infection subjects affected / exposed occurrences (all) $0 / 2 (0.00\%)$ $0 / 3 (0.00\%)$ $0 / 17 (0.00\%)$	Skin candida			
Tooth abscess subjects affected / exposed occurrences (all) $0/2 (0.00\%)$ 0 $0/3 (0.00\%)$ 0 $0/17 (0.00\%)$ 0Upper respiratory tract infection subjects affected / exposed occurrences (all) $0/2 (0.00\%)$ 0 $1/3 (33.33\%)$ 0 $0/17 (0.00\%)$ 0Urinary tract infection subjects affected / exposed occurrences (all) $0/2 (0.00\%)$ 		0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Upper respiratory tract infection subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     0 / 17 (0.00%)       0     1     3 (33.33%)     0 / 17 (0.00%)     0     1       Urinary tract infection subjects affected / exposed     0 / 2 (0.00%)     2 / 3 (66.67%)     1 / 17 (5.88%)       occurrences (all)     0     2     1     1       Varicella subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Vascular device infection subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Vulvovaginal mycotic infection subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	0	0	0
occurrences (all)000Upper respiratory tract infection subjects affected / exposed $0/2 (0.00\%)$ $1/3 (33.33\%)$ $0/17 (0.00\%)$ occurrences (all)010Urinary tract infection subjects affected / exposed $0/2 (0.00\%)$ $2/3 (66.67\%)$ $1/17 (5.88\%)$ occurrences (all)021Varicella subjects affected / exposed $0/2 (0.00\%)$ $0/3 (0.00\%)$ $0/17 (0.00\%)$ occurrences (all)0 $0/3 (0.00\%)$ $0/17 (0.00\%)$ vascular device infection subjects affected / exposed $0/2 (0.00\%)$ $0/3 (0.00\%)$ $0/17 (0.00\%)$ vascular device infection subjects affected / exposed $0/2 (0.00\%)$ $0/3 (0.00\%)$ $0/17 (0.00\%)$ vulvovaginal mycotic infection subjects affected / exposed $0/2 (0.00\%)$ $0/3 (0.00\%)$ $0/17 (0.00\%)$	Tooth abscess			
Upper respiratory tract infection subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     0 / 17 (0.00%)       occurrences (all)     0     1     0       Urinary tract infection subjects affected / exposed     0 / 2 (0.00%)     2 / 3 (66.67%)     1 / 17 (5.88%)       occurrences (all)     0     2     1       Varicella subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     1       Varicella subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       occurrences (all)     0     0     0     0     0     0       Vascular device infection subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       vulvovaginal mycotic infection subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     1 / 3 (33.33%)     0 / 17 (0.00%)       occurrences (all)     0     1     0       Urinary tract infection     0 / 2 (0.00%)     2 / 3 (66.67%)     1 / 17 (5.88%)       occurrences (all)     0     2     1       Varicella     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       varicella     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Vascular device infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       occurrences (all)     0     0     0     0     0       Vulvovaginal mycotic infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0	occurrences (all)	0	0	0
occurrences (all)     0     1     0       Urinary tract infection subjects affected / exposed occurrences (all)     0 / 2 (0.00%)     2 / 3 (66.67%)     1 / 17 (5.88%)       Varicella subjects affected / exposed occurrences (all)     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       Varicella subjects affected / exposed occurrences (all)     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       Vascular device infection subjects affected / exposed occurrences (all)     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       Vulvovaginal mycotic infection subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	Upper respiratory tract infection			
Urinary tract infection subjects affected / exposed     0 / 2 (0.00%)     2 / 3 (66.67%)     1 / 17 (5.88%)       occurrences (all)     0     2     1       Varicella subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Varicella subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Vascular device infection subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Vulvovaginal mycotic infection subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     2 / 3 (66.67%)     1 / 17 (5.88%)       occurrences (all)     0     2     1       Varicella     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Vascular device infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       vulvovaginal mycotic infection     0     0     0 / 3 (0.00%)     0 / 17 (0.00%)       vulvovaginal mycotic infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	0	1	0
occurrences (all)     0     2     1       Varicella     subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0     0       Vascular device infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       Vascular device infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       Vulvovaginal mycotic infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	Urinary tract infection			
Varicella     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Vascular device infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       Vascular device infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)     0       Vulvovaginal mycotic infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	1 / 17 (5.88%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Vascular device infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Vulvovaginal mycotic infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	0	2	1
occurrences (all)000Vascular device infection subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Vulvovaginal mycotic infection subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)	Varicella			
Vascular device infection subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)occurrences (all)0000Vulvovaginal mycotic infection subjects affected / exposed0 / 2 (0.00%)0 / 3 (0.00%)0 / 17 (0.00%)	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       occurrences (all)     0     0     0     0       Vulvovaginal mycotic infection     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)       subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	0	0	0
occurrences (all)   0   0   0     Vulvovaginal mycotic infection subjects affected / exposed   0 / 2 (0.00%)   0 / 3 (0.00%)   0 / 17 (0.00%)	Vascular device infection			
Vulvovaginal mycotic infection       subjects affected / exposed       0 / 2 (0.00%)       0 / 3 (0.00%)       0 / 17 (0.00%)	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
subjects affected / exposed     0 / 2 (0.00%)     0 / 3 (0.00%)     0 / 17 (0.00%)	occurrences (all)	0	0	0
	Vulvovaginal mycotic infection			
occurrences (all) 0 0 0	subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 17 (0.00%)
	occurrences (all)	0	0	0

Non-serious adverse events	Gastric
Total subjects affected by non-serious adverse events	
subjects affected / exposed	12 / 12 (100.00%)
Vascular disorders	
Deep vein thrombosis	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Flushing	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Hot flush	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0

I	1		
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Jugular vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Raynaud's phenomenon			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)			
Thrombophlebitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Neoplasms benign, malignant and			
unspecified (incl cysts and polyps)			
Haemangioma subjects affected / exposed			
	0 / 12 (0.00%)		
occurrences (all)	0		
Skin papilloma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Tumour flare subjects affected / exposed			
	0 / 12 (0.00%)		
occurrences (all)	0		
Tumour pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
	1	•	· · · · · · · · · · · · · · · · · · ·

subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
General disorders and administration site conditions		
Asthenia		
subjects affected / exposed	6 / 12 (50.00%)	
occurrences (all)	11	
Catheter site pain		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Chest pain		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)	1	
Chills		
subjects affected / exposed	3 / 12 (25.00%)	
occurrences (all)	4	
Cyst		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Fatigue		
subjects affected / exposed	3 / 12 (25.00%)	
occurrences (all)	3	
Gait disturbance		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Gravitational oedema		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Influenza like illness		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)	1	
Malaise		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)	1	
Mucosal dryness		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	

		,	
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Oedema			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	8 / 12 (66.67%)		
occurrences (all)	14		
Swelling			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Temperature regulation disorder			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Localised oedema subjects affected / exposed	1/10/0 220/1		
occurrences (all)	1 / 12 (8.33%)		
	1		
Psychiatric disorders			
Anxiety subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0 / 12 (0.00%)		
Bradyphrenia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0	
Depression		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Insomnia		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Mania		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
	-	
Panic attack		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Paranoia		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
	Ĵ	
Reproductive system and breast disorders		
Penile rash		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Decisional		
Prostatitis subjects affected / exposed	0 / 12 /0 000()	
	0 / 12 (0.00%)	
occurrences (all)	0	
Injury, poisoning and procedural		
complications Incision site pain		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Infusion related reaction		
subjects affected / exposed	3 / 12 (25.00%)	
occurrences (all)	4	
Joint injury		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
	0	
Procedural pain		
subjects affected / exposed	0 / 12 (0.00%)	

occurrences (all)	0	
Skin abrasion subjects affected / exposed		
	0 / 12 (0.00%)	
occurrences (all)	0	
nvestigations		
Activated partial thromboplastin time prolonged	2	
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Alanine aminotransferase increased		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)		
	0	
Aspartate aminotransferase increased		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)	1	
Blood albumin decreased		
subjects affected / exposed	0 / 12 (0 00%)	
	0 / 12 (0.00%)	
occurrences (all)	0	
Blood alkaline phosphatase increased	1	
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)		
	1	
Blood bilirubin increased		
subjects affected / exposed	2 / 12 (16.67%)	
occurrences (all)	2	
Blood creatine phosphokinase increased		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Blood creatinine increased		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)		
	2	
Blood fibrinogen decreased		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
	0	
Blood lactate dehydrogenase increased		

occurrences (all)	l o		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase			
abnormal subjects affected / exposed			
occurrences (all)	1 / 12 (8.33%)		
	1		
Lymphocyte count decreased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Platelet count decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Serum ferritin decreased			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
	, , , , , , , , , , , , , , , , , , ,		
Cardiac disorders Angina pectoris			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0 / 12 (0.00 %)		
()			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Atrial flutter			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Sinus tachycardia subjects affected / exposed occurrences (all) Tachycardia subjects affected / exposed occurrences (all) Ventricular fibrillation	0 / 12 (0.00%) 0 0 / 12 (0.00%)		
--	---------------------------------------	--	
Tachycardia subjects affected / exposed occurrences (all)	0 0 / 12 (0.00%)		
Tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%)		
subjects affected / exposed occurrences (all)			
occurrences (all)			
Ventricular fibrillation	0		
Ventricular fibrillation			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal			
lisorders			
Aphonia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
A share			
Asthma			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bronchospasm			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
	0		
Catarrh			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Cough subjects affected / exposed			
	1 / 12 (8.33%)		
occurrences (all)	1		
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
	U		
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	3		
Epistaxis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Нурохіа			
subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0	
Nasal congestion		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Oropharyngeal pain		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Pleural effusion		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Pneumonitis		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Pneumothorax		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Productive cough		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
D. I		
Pulmonary embolism subjects affected / exposed	0 / 12 /0 000/ )	
	0 / 12 (0.00%)	
occurrences (all)	0	
Sputum discoloured		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)	1	
Throat irritation		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)	1	
Upper-airway cough		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Wheeting		
Wheezing subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
	Ĭ	

Anaemia	1
subjects affected / exposed	3 / 12 (25.00%)
occurrences (all)	3
lumahanar:-	
Lymphopenia subjects affected / exposed	1 / 12 (9 220/)
occurrences (all)	1 / 12 (8.33%)
	1
Thrombocytopenia	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Thrombocytosis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
	-
Nervous system disorders Disturbance in attention	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Dizziness	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Dysaesthesia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
	-
Dysarthria	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Dysgeusia	
subjects affected / exposed	4 / 12 (33.33%)
occurrences (all)	5
Headache subjects affected / exposed	1 / 12 (0 220/)
	1 / 12 (8.33%)
occurrences (all)	1
Hemianopia homonymous	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Hyporposthesia	
Hyperaesthesia subjects affected / exposed	0 / 12 (0.00%)

Monoparesis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Neuropathy peripheral subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Peripheral sensory neuropathy subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Psychomotor hyperactivity subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Somnolence subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Syncope subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Paraesthesia subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye disorders Dry eye subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye puritis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye disorders Dry eye subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye disorders Dry eye subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eyelid oedema subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eyelid oedema subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Or hital myositis       0 / 12 (0.00%)	occurrences (all)	0	
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Neuropathy peripheral       0 / 12 (0.00%)         occurrences (all)       0         Peripheral sensory neuropathy       0 / 12 (0.00%)         occurrences (all)       0         Psychomotor hyperactivity       0 / 12 (0.00%)         occurrences (all)       0         Somnolence       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0 </td <td>Manananaia</td> <td></td> <td></td>	Manananaia		
occurrences (all)       0         Neuropathy peripheral subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Peripheral sensory neuropathy subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Psychomotor hyperactivity subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Somnolence subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Paraesthesia subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Paraesthesia subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Eye disorders Dry eye subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Eye pruntis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Eyelid oedema subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)         Lacrimation increased subjects affected / exposed occurrences (all)       0 / 12 (0.00%) occurrences (all)		0 / 12 (0 00%)	
Neuropathy peripheral subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Peripheral sensory neuropathy subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Psychomotor hyperactivity subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Somnolence subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Syncope subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Paraesthesia subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye disorders Dry eye subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 0         Eye disorders Dry eye subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye prunitis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eyelid oedema subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Lacrimation increased subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0			
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Peripheral sensory neuropathy       0 / 12 (0.00%)         occurrences (all)       0         Psychomotor hyperactivity       0 / 12 (0.00%)         occurrences (all)       0         Somnolence       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         occurrences (all)       0         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         ocurrences (all)		0	
occurrences (all)       0         Peripheral sensory neuropathy subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Psychomotor hyperactivity subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Somnolence subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       1         Paraesthesia subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       1         Eye prunitis subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0			
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Psychomotor hyperactivity subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Somnolence subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Syncope subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 0         Paraesthesia subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye disorders       0 / 12 (0.00%) 0         Dry eye subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye pruritis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eyelid oedema subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Lacrimation increased subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0	subjects affected / exposed	0 / 12 (0.00%)	
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Psychomotor hyperactivity       0 / 12 (0.00%)         occurrences (all)       0         Somnolence       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye       subjects affected / exposed         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         occurrences (all)       1         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0	occurrences (all)	0	
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Psychomotor hyperactivity       0 / 12 (0.00%)         occurrences (all)       0         Somnolence       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye       subjects affected / exposed         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       1         Eye disorders       1         Dry eye       subjects affected / exposed         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Eye prunitis       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0	Peripheral sensory neuropathy		
occurrences (all)0Psychomotor hyperactivity subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Somnolence subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Syncope subjects affected / exposed occurrences (all)1 / 12 (8.33%) 0Paraesthesia subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eye disorders Dry eye subjects affected / exposed occurrences (all)1 / 12 (8.33%) 0Eye disorders Dry eye subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eye disorders Dry eye subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eye pruritis subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eyelid oedema subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Lacrimation increased subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0		0 / 12 (0.00%)	
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Somnolence       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye       subjects affected / exposed         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       1         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0	occurrences (all)		
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Somnolence       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         occurrences (all)       1         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0			
occurrences (all)       0         Somnolence       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         occurrences (all)       1         Eye prunitis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0			
Somnolence       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       1 / 12 (8.33%)         occurrences (all)       1         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       1         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Lyclid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0			
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Syncope       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (0.00%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         occurrences (all)       0         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0	occurrences (an)	0	
occurrences (all)       0         Syncope subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 1         Paraesthesia subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eye disorders Dry eye subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 1         Eye pruritis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Eyelid oedema subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Lacrimation increased subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0	Somnolence		
Syncope       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (0.00%)         occurrences (all)       0         Paraesthesia       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       0 / 12 (0.00%)         Dry eye       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       0 / 12 (0.00%)         occurrences (all)       0         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0	subjects affected / exposed	0 / 12 (0.00%)	
subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       1 / 12 (8.33%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye privitis       1 / 12 (8.33%)         occurrences (all)       1         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0	occurrences (all)	0	
subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Paraesthesia       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       1 / 12 (8.33%)         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye disorders       1 / 12 (8.33%)         occurrences (all)       1         Eye proves       1 / 12 (8.33%)         occurrences (all)       0         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0         0       0 / 12 (0.00%)         occurrences (all)       0	Syncope		
occurrences (all)1Paraesthesia subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eye disorders Dry eye subjects affected / exposed occurrences (all)1 / 12 (8.33%) 1Eye pruritis subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eyelid oedema subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eyelid oedema subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Lacrimation increased subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0		1 / 12 (8.33%)	
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Eye disorders       1 / 12 (8.33%)         Dry eye       1 / 12 (8.33%)         subjects affected / exposed       1         Eye pruritis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         occurrences (all)       0	occurrences (all)		
subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eye disorders Dry eye subjects affected / exposed occurrences (all)1 / 12 (8.33%) 1Eye pruritis subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eyelid oedema subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eyelid oedema subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Lacrimation increased subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0			
occurrences (all)       0         Eye disorders       0         Dry eye       1 / 12 (8.33%)         occurrences (all)       1         Eye pruritis       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Eyelid oedema       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0			
Eye disorders         Dry eye         subjects affected / exposed         occurrences (all)         Eye pruritis         subjects affected / exposed         occurrences (all)         Eye pruritis         subjects affected / exposed         occurrences (all)         Eyelid oedema         subjects affected / exposed         o/ 12 (0.00%)         occurrences (all)         0         Lacrimation increased         subjects affected / exposed         o/ 12 (0.00%)         occurrences (all)         0			
Dry eye subjects affected / exposed1 / 12 (8.33%) 1occurrences (all)1Eye pruritis subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Eyelid oedema subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Lacrimation increased subjects affected / exposed0 / 12 (0.00%) 0Lacrimation increased subjects affected / exposed0 / 12 (0.00%) 000	occurrences (air)	0	
subjects affected / exposed1 / 12 (8.33%)occurrences (all)1Eye pruritis subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Eyelid oedema subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Lacrimation increased subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0	•		
occurrences (all)1Eye pruritis subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Eyelid oedema subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Lacrimation increased subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0			
Eye pruritis subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Eyelid oedema subjects affected / exposed0 / 12 (0.00%) 0ccurrences (all)0Lacrimation increased subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0			
subjects affected / exposed0 / 12 (0.00%)occurrences (all)0Eyelid oedema subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Lacrimation increased subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0	occurrences (all)	1	
occurrences (all)0Eyelid oedema subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0Lacrimation increased subjects affected / exposed0 / 12 (0.00%) 0occurrences (all)0	Eye pruritis		
Eyelid oedema         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Lacrimation increased       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0	subjects affected / exposed	0 / 12 (0.00%)	
subjects affected / exposed0 / 12 (0.00%)occurrences (all)0Lacrimation increased0 / 12 (0.00%)subjects affected / exposed0 / 12 (0.00%)occurrences (all)0	occurrences (all)	0	
subjects affected / exposed0 / 12 (0.00%)occurrences (all)0Lacrimation increased0 / 12 (0.00%)subjects affected / exposed0 / 12 (0.00%)occurrences (all)0	Evelid oedema		
occurrences (all)0Lacrimation increased subjects affected / exposed0 / 12 (0.00%)occurrences (all)0		0 / 12 (0.00%)	
Lacrimation increased subjects affected / exposed 0 / 12 (0.00%) occurrences (all) 0	occurrences (all)		
subjects affected / exposed0 / 12 (0.00%)occurrences (all)0			
occurrences (all) 0			
Orbital myositis	occurrences (all)	0	
	Orbital myositis		

subjects affected / exposed	0 / 12 (0.00%)	ľ	l
occurrences (all)			
	0		
Periorbital swelling			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Retinal artery occlusion			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)			
	0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
<b>_</b>			
Tinnitus subjects affected / exposed			
	0 / 12 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)			
	0		
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed			
	0 / 12 (0.00%)	l	

occurrences (all)	0
Atrophic glossitis subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Colitis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Constipation	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Diarrhoea	
subjects affected / exposed	8 / 12 (66.67%)
occurrences (all)	16
Dry mouth	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Dyspepsia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Dysphagia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Enteritis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Gastritis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Gastrointestinal pain	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Glossitis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Haematochezia	
subjects affected / exposed	0 / 12 (0.00%)

occurrences (all)	0
Haemorrhoids	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
	Ū
Lower gastrointestinal haemorrhage	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Nausea	
subjects affected / exposed	8 / 12 (66.67%)
occurrences (all)	12
Odynophagia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Rectal haemorrhage	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Salivary hypersecretion subjects affected / exposed	0 / 12 /0 00%)
occurrences (all)	0 / 12 (0.00%)
	0
Stomatitis	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Toothache	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
	U U
Vomiting	
subjects affected / exposed	7 / 12 (58.33%)
occurrences (all)	8
Renal and urinary disorders	
Acute kidney injury	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Anuria	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
(,	U
Dysuria	

accurrences (all)       1         Leukocyturia       0 / 12 (0.00%)         occurrences (all)       0         Nephritis       0 / 12 (0.00%)         occurrences (all)       0         Pollakluria       0 / 12 (0.00%)         occurrences (all)       0         Pollakluria       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       subjects affected / exposed         ocurrences (all)       0         Erythema       1 / 12 (8.33%)         ocurrences (all)       0         Erythema       1 / 12 (0.00%)	subjects affected / exposed	1 / 12 (9 220/)		
Leukocyturia       0 / 12 (0.00%)         occurrences (all)       0         Nephritis       0 / 12 (0.00%)         occurrences (all)       0         Pollakiuria       0 / 12 (0.00%)         occurrences (all)       0         Pollakiuria       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occ		1 / 12 (8.33%)		
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Nephritis       subjects affected / exposed         occurrences (all)       0         Pollakiuria       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       0 / 12 (0.00%)         occurrences (all)       0         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%) <td></td> <td></td> <td></td> <td></td>				
occurrences (all)       0         Nephritis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Pollakiuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Polyuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Proteinuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Renal failure subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Hepatobiliary disorders Cholestasis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Portal vein thrombosis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Erythema subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 0         Hair colour changes       1 / 12 (8.33%) 2	Leukocyturia			
Nephritis       0 / 12 (0.00%)         subjects affected / exposed       0         pollakiuria       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0       0         Erythema       1 / 12 (8.33%)       0         subjects affected / exposed       1 / 12 (8.33%)       2	subjects affected / exposed	0 / 12 (0.00%)		
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Pollakiuria       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       1 / 12 (8.33%)         occurrences (all)       0         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)	occurrences (all)	0		
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Pollakiuria       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       1 / 12 (8.33%)         occurrences (all)       0         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)	N 1			
occurrences (all)       0         Pollakiuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Polyuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Proteinuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Renal failure subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Renal failure subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Portal vein thrombosis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Portal vein thrombosis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Erythema subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 0         Hair colour changes       1 / 12 (8.33%)		0 / 12 (0 00%)		
Pollakiuria       subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       subjects affected / exposed         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1				
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Polyuria       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       0         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)		0		
occurrences (all)       0         Polyuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Proteinuria subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Renal failure subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 1         Hepatobiliary disorders Cholestasis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Portal vein thrombosis subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed occurrences (all)       0 / 12 (0.00%) 0         Erythema subjects affected / exposed occurrences (all)       1 / 12 (8.33%) 2         Hair colour changes       1 / 12 (8.33%)	Pollakiuria			
Polyuria       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       subjects affected / exposed         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Hepatobillary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1	subjects affected / exposed	0 / 12 (0.00%)		
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)         occurrences (all)       2	occurrences (all)	0		
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Proteinuria       subjects affected / exposed         occurrences (all)       0         Renal failure       1 / 12 (0.00%)         subjects affected / exposed       1 / 12 (0.00%)         occurrences (all)       1         Hepatobillary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)	Polyuria			
occurrences (all)       0         Proteinuria       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)         uccurrences (all)       2		0 / 12 (0.00%)		
Proteinuria       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       1 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)				
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Renal failure       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (0.00%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)         occurrences (all)       2	()			
occurrences (all)       0         Renal failure       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)				
Renal failure       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)	subjects affected / exposed	0 / 12 (0.00%)		
subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)	occurrences (all)	0		
subjects affected / exposed       1 / 12 (8.33%)         occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)	Renal failure			
occurrences (all)       1         Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       0 / 12 (0.00%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)         Pair colour changes       1 / 12 (8.33%)		1 / 12 (8.33%)		
Hepatobiliary disorders       0 / 12 (0.00%)         Cholestasis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)	occurrences (all)			
Cholestasis       0 / 12 (0.00%)         subjects affected / exposed       0         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       0 / 12 (0.00%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)         Attic to fully the set				
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       0 / 12 (0.00%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)         Occurrences (all)       2				
occurrences (all)       0         Portal vein thrombosis       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0 / 12 (0.00%)         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       0 / 12 (0.00%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)         Occurrences (all)       2		0 / 12 (0 00%)		
Portal vein thrombosis       0 / 12 (0.00%)         occurrences (all)       0         Skin and subcutaneous tissue disorders       0         Dry skin       0 / 12 (0.00%)         occurrences (all)       0         Erythema       0 / 12 (0.00%)         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Hair colour changes       1 / 12 (8.33%)				
subjects affected / exposed occurrences (all)0 / 12 (0.00%) 0Skin and subcutaneous tissue disorders Dry skin subjects affected / exposed0 / 12 (0.00%) 0Occurrences (all)0 / 12 (0.00%) 0Erythema subjects affected / exposed occurrences (all)1 / 12 (8.33%) 2Hair colour changes2		U		
occurrences (all)       0         Skin and subcutaneous tissue disorders       0         Dry skin       0         subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)	Portal vein thrombosis			
Skin and subcutaneous tissue disorders       Dry skin       subjects affected / exposed       occurrences (all)       Erythema       subjects affected / exposed       occurrences (all)       I / 12 (8.33%)       occurrences (all)       Pair colour changes	subjects affected / exposed	0 / 12 (0.00%)		
Dry skin     0 / 12 (0.00%)       occurrences (all)     0       Erythema     1 / 12 (8.33%)       occurrences (all)     2	occurrences (all)	0		
Dry skin     0 / 12 (0.00%)       occurrences (all)     0       Erythema     1 / 12 (8.33%)       occurrences (all)     2	Skin and subcutaneous tissue disorders			
subjects affected / exposed       0 / 12 (0.00%)         occurrences (all)       0         Erythema       1 / 12 (8.33%)         occurrences (all)       2         Hair colour changes       1 / 12 (8.33%)				
Erythema subjects affected / exposed 1 / 12 (8.33%) occurrences (all) 2 Hair colour changes		0 / 12 (0.00%)		
subjects affected / exposed     1 / 12 (8.33%)       occurrences (all)     2       Hair colour changes     1	occurrences (all)	0		
subjects affected / exposed     1 / 12 (8.33%)       occurrences (all)     2       Hair colour changes     1				
occurrences (all) 2 Hair colour changes		1 / 12 /0 220/ )		
Hair colour changes				
	occurrences (all)	2		
subjects affected / exposed 0 / 12 (0.00%)	Hair colour changes			
	subjects affected / exposed	0 / 12 (0.00%)		

occurrences (all)	0
Hyperhidrosis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Hypohidrosis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Palmar-plantar erythrodysaesthaesia syndrome	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	3
Papule	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
	U
Pruritis	
subjects affected / exposed	3 / 12 (25.00%)
occurrences (all)	4
Rash	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	3
Rash erythematous	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Rash maculo-papular	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
	0
Rash pruritic	
subjects affected / exposed	2 / 12 (16.67%)
occurrences (all)	3
Skin exfoliation	
subjects affected / exposed	2 / 12 (16.67%)
occurrences (all)	2
Skin lesion	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Solar dermatitis	

subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue			
disorders Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	6		
	0		
Arthritis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)			
	1		
Dactylitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
	0		
Immune-mediated arthritis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle contracture			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

	I
Musculoskeletal chest pain	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Musculoskeletal pain	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Myalgia	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Neck pain	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Pain in extremity	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Spondulitie	
Spondylitis subjects affected / exposed	1/10/0000/\
	1 / 12 (8.33%)
occurrences (all)	1
Endocrine disorders	
Hyperthyroidism	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Hypothyroidism subjects affected / exposed	
	0 / 12 (0.00%)
occurrences (all)	0
Metabolism and nutrition disorders	
Cachexia	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	1
Decreased associate	
Decreased appetite subjects affected / exposed	2/12/16(570/)
	2 / 12 (16.67%)
occurrences (all)	2
Dehydration	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Diabetes mellitus	I

subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Hypercholesterolaemia		
subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Hyperglycaemia		
subjects affected / exposed	1 / 12 (8.33%)	
occurrences (all)	1	
Hyporkalaomia		
Hyperkalaemia subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Hypertriglyceridaemia subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Hypoalbuminaemia subjects affected / exposed	4 / 12 (33.33%)	
occurrences (all)	4	
It we extra and a		
Hypocalcaemia subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Hypoglycaemia subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0	
Hypokalaemia subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0 / 12 (0.00 %)	
	, v	
Hypomagnasaemia subjects affected / exposed	0 / 12 (0.00%)	
occurrences (all)	0 / 12 (0.00%)	
	, v	
Polydipsia subjects affected / exposed	0 / 12 /0 00%	
occurrences (all)	0 / 12 (0.00%) 0	
	0	
Vitamin B12 deficiency subjects affected / exposed		
occurrences (all)	0 / 12 (0.00%)	
	0	
Vitamin B6 deficiency		

subjects affected / exposed	0 / 10 /0 000/	1	1
	0 / 12 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)			
	0		
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
	Ŭ		
nfections and infestations			
Abscess limb			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		
To Change and			
Influenza subjects affected / exposed			
	0 / 12 (0.00%)		
occurrences (all)	0		
Lip infection			
subjects affected / exposed	0 / 12 /0 000/ )		
	0 / 12 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)			
	1		
Nasopharyngitis			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)			
	4		
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)		
occurrences (all)	0		

Oral herpes	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Oropharyngeal candidiasis	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
	0
Paronychia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Dhommaitic	
Pharyngitis subjects affected / exposed	0 / 12 (0 00%)
	0 / 12 (0.00%)
occurrences (all)	0
Pneumonia	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Respiratory tract infection	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Circustia	
Sinusitis subjects affected / exposed	
	0 / 12 (0.00%)
occurrences (all)	0
Skin candida	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Tooth abscess	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0
Upper respiratory tract infection	
Upper respiratory tract infection subjects affected / exposed	
	0 / 12 (0.00%)
occurrences (all)	0
Urinary tract infection	
subjects affected / exposed	1 / 12 (8.33%)
occurrences (all)	
Varicella	
subjects affected / exposed	0 / 12 (0.00%)
occurrences (all)	0

Vascular device infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 February 2016	Changes to eligibility criteria
11 May 2016	Changes to eligibility criteria
13 December 2016	Add new biomarker cohort
03 August 2017	Increased sample size; changes to eligibility criteria
14 April 2018	Add pretreatment cohorts; updates to eligibility criteria; increased sample size
24 September 2018	Updates to enrollment and eligibility criteria; remove obinutuzumab pretreatment
18 May 2019	Changes to secondary outcome measures

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The final study report was abbreviated due to early study termination due to non-safety reasons.

Notes: