



Clinical trial results:

A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + Umbralisib With or Without Bendamustine and Umbralisib Alone in Patients With Previously Treated Non-Hodgkin's Lymphoma

Summary

EudraCT number	2016-004718-90
Trial protocol	GB PL SK ES IT
Global end of trial date	04 July 2022

Results information

Result version number	v1 (current)
This version publication date	19 July 2023
First version publication date	19 July 2023

Trial information

Trial identification

Sponsor protocol code	UTX-TGR-205
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02793583
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	TG Therapeutics, Inc
Sponsor organisation address	2 Gansevoort St., 9th Floor, New York, NY 10014, United States,
Public contact	Izabela Kozdraś-Urbaneck, Brillance Sp. z o.o., +48 668166876, ikozdras@brillance.pl
Scientific contact	Izabela Kozdraś-Urbaneck, Brillance Sp. z o.o., +48 668166876, ikozdras@brillance.pl

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	04 July 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	04 July 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

Unity NHL - A Phase 2b randomised study to assess the efficacy and safety of the combination of ublituximab + umbralisib with or without bendamustine and umbralisib alone in subjects with previously treated non-hodgkin's lymphoma.

The purpose of this study was to evaluate the efficacy and safety of umbralisib monotherapy and the umbralisib + ublituximab (U2) combination in aggressive and indolent lymphomas and to also explore the U2 regimen in combination with bendamustine in the treatment of non-Hodgkin lymphomas (NHL) (follicular lymphoma (FL), small lymphocytic lymphoma (SLL), marginal zone lymphoma (MZL), diffuse large B-cell lymphoma (DLBCL) and mantle cell lymphoma (MCL).

Protection of trial subjects:

All study subjects were required to read and sign an informed consent form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 May 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Slovakia: 10
Country: Number of subjects enrolled	Spain: 15
Country: Number of subjects enrolled	United Kingdom: 45
Country: Number of subjects enrolled	Italy: 43
Country: Number of subjects enrolled	Australia: 29
Country: Number of subjects enrolled	Israel: 34
Country: Number of subjects enrolled	Poland: 94
Country: Number of subjects enrolled	United States: 449
Country: Number of subjects enrolled	Korea, Republic of: 16
Worldwide total number of subjects	735
EEA total number of subjects	162

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)	277
From 65 to 84 years	418
85 years and over	40

Subject disposition

Recruitment

Recruitment details:

A total of 735 subjects took part in the study at 141 investigative sites in Australia, Israel, Italy, Poland, Slovakia, South Korea, Spain, the United Kingdom, and the United States from 25 May 2016 to 4 July 2022.

Pre-assignment

Screening details:

After screening, a total of 735 subjects were enrolled in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A: Ublituximab + Umbralisib (TGR-1202)

Arm description:

Subjects with FL, MZL, MCL, and DLBCL received ublituximab, 900 milligrams (mg), intravenous (IV), infusion on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6, and thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg, orally, once daily, through Cycles 1-24 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.

Arm type	Experimental
Investigational medicinal product name	Ublituximab
Investigational medicinal product code	
Other name	TG-1101
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ublituximab, 900 mg, was administered as IV infusion

Investigational medicinal product name	Umbralisib
Investigational medicinal product code	
Other name	TGR-1202
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Umbralisib, 800 mg, tablet was administered orally

Arm title	Arm B: Umbralisib (TGR-1202) Monotherapy
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Arm description:

Subjects with FL, SLL, MZL, MCL, and DLBCL received umbralisib 800 mg orally, once daily through Cycles 1-24 (1 cycle=28 days), or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.

Arm type	Experimental
Investigational medicinal product name	Umbralisib
Investigational medicinal product code	
Other name	TGR-1202
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Umbralisib, 800 mg, tablet was administered orally

Arm title	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
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Arm description:

Subjects with DLBCL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg orally, once daily through Cycles 1-24 and bendamustine 90 milligrams per square meter (mg/m²), IV infusion, on Days 1 and 2 of Cycles 1-6 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.

Arm type	Experimental
Investigational medicinal product name	Ublituximab
Investigational medicinal product code	
Other name	TG-1101
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ublituximab, 900 mg, was administered as IV infusion

Investigational medicinal product name	Umbralisib
Investigational medicinal product code	
Other name	TGR-1202
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Umbralisib, 800 mg, tablet was administered orally

Investigational medicinal product name	Bendamustine
Investigational medicinal product code	
Other name	Treanda
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Bendamustine, 100 mg, was administered as IV infusion

Arm title	Arm D: Ublituximab Monotherapy
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Arm description:

Subjects with FL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.

Arm type	Experimental
Investigational medicinal product name	Ublituximab
Investigational medicinal product code	
Other name	TG-1101
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ublituximab, 900 mg, was administered as IV infusion

Arm title	Arm E: Ublituximab to Umbralisib (TGR-1202)
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Arm description:

Subjects in Arm D were crossed over to umbralisib monotherapy upon confirmation of progressive disease (PD) by the independent review committee (IRC) to receive umbralisib, 800 mg orally, once daily, through Cycles 1-24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.

Arm type	Experimental
Investigational medicinal product name	Umbralisib
Investigational medicinal product code	
Other name	TGR-1202
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Umbralisib, 800 mg, tablet was administered orally

Number of subjects in period 1	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
Started	262	307	130
Completed	0	0	0
Not completed	262	307	130
Adverse Event	5	13	7
Completion of Protocol Specified Regimen	1	-	1
Investigator Decision	22	32	10
Study Terminated by Sponsor	56	32	7
Withdrawal of Consent	15	19	12
Unknown/Missing	1	1	-
Non-compliance with Study	1	1	2
Death	34	18	13
Progressive Disease	108	173	73
Lost to follow-up	1	-	1
Reason not Specified	6	4	3
Initiation of Non-protocol Anti-cancer Therapy	10	8	1
Lack of efficacy	2	6	-

Number of subjects in period 1	Arm D: Ublituximab Monotherapy	Arm E: Ublituximab to Umbralisib (TGR-1202)
Started	24	12
Completed	0	0
Not completed	24	12
Adverse Event	-	-
Completion of Protocol Specified Regimen	-	-
Investigator Decision	2	5
Study Terminated by Sponsor	1	1
Withdrawal of Consent	2	-
Unknown/Missing	-	-

Non-compliance with Study	-	-
Death	2	1
Progressive Disease	17	4
Lost to follow-up	-	-
Reason not Specified	-	-
Initiation of Non-protocol Anti-cancer Therapy	-	1
Lack of efficacy	-	-

Baseline characteristics

Reporting groups

Reporting group title	Arm A: Ublituximab + Umbralisib (TGR-1202)
Reporting group description: Subjects with FL, MZL, MCL, and DLBCL received ublituximab, 900 milligrams (mg), intravenous (IV), infusion on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6, and thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg, orally, once daily, through Cycles 1-24 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.	
Reporting group title	Arm B: Umbralisib (TGR-1202) Monotherapy
Reporting group description: Subjects with FL, SLL, MZL, MCL, and DLBCL received umbralisib 800 mg orally, once daily through Cycles 1-24 (1 cycle=28 days), or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.	
Reporting group title	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
Reporting group description: Subjects with DLBCL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg orally, once daily through Cycles 1-24 and bendamustine 90 milligrams per square meter (mg/m ²), IV infusion, on Days 1 and 2 of Cycles 1-6 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.	
Reporting group title	Arm D: Ublituximab Monotherapy
Reporting group description: Subjects with FL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.	
Reporting group title	Arm E: Ublituximab to Umbralisib (TGR-1202)
Reporting group description: Subjects in Arm D were crossed over to umbralisib monotherapy upon confirmation of progressive disease (PD) by the independent review committee (IRC) to receive umbralisib, 800 mg orally, once daily, through Cycles 1-24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.	

Reporting group values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
Number of subjects	262	307	130
Age categorical Units: Subjects			
Adults (18-64 years)	87	131	40
From 65-84 years	158	164	79
85 years and over	17	12	11
Age continuous Units: years			
arithmetic mean	68.4	66.0	69.6
standard deviation	± 11.15	± 11.13	± 11.25
Gender categorical Units: Subjects			
Female	105	139	52
Male	157	168	78

Race			
Units: Subjects			
White	211	256	114
Black or African American	8	12	5
Asian	12	10	4
American Indian or Alaska Native	0	2	0
Native Hawaiian or Other Pacific Islander	0	2	0
Multiple	2	0	0
Other	3	5	0
Not Reported	26	20	7
Ethnicity			
Units: Subjects			
Hispanic or Latino	18	15	2
Not Hispanic or Latino	210	268	115
Not Reported	34	24	13

Reporting group values	Arm D: Ublituximab Monotherapy	Arm E: Ublituximab to Umbralisib (TGR-1202)	Total
Number of subjects	24	12	735
Age categorical			
Units: Subjects			
Adults (18-64 years)	13	6	277
From 65-84 years	11	6	418
85 years and over	0	0	40
Age continuous			
Units: years			
arithmetic mean	62.9	62.8	
standard deviation	± 10.63	± 10.26	-
Gender categorical			
Units: Subjects			
Female	8	4	308
Male	16	8	427
Race			
Units: Subjects			
White	19	9	609
Black or African American	1	1	27
Asian	0	0	26
American Indian or Alaska Native	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	2
Multiple	0	0	2
Other	0	0	8
Not Reported	4	2	59
Ethnicity			
Units: Subjects			
Hispanic or Latino	2	1	38
Not Hispanic or Latino	19	11	623
Not Reported	3	0	74

End points

End points reporting groups

Reporting group title	Arm A: Ublituximab + Umbralisib (TGR-1202)
Reporting group description: Subjects with FL, MZL, MCL, and DLBCL received ublituximab, 900 milligrams (mg), intravenous (IV), infusion on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6, and thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg, orally, once daily, through Cycles 1-24 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.	
Reporting group title	Arm B: Umbralisib (TGR-1202) Monotherapy
Reporting group description: Subjects with FL, SLL, MZL, MCL, and DLBCL received umbralisib 800 mg orally, once daily through Cycles 1-24 (1 cycle=28 days), or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.	
Reporting group title	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
Reporting group description: Subjects with DLBCL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg orally, once daily through Cycles 1-24 and bendamustine 90 milligrams per square meter (mg/m ²), IV infusion, on Days 1 and 2 of Cycles 1-6 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.	
Reporting group title	Arm D: Ublituximab Monotherapy
Reporting group description: Subjects with FL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.	
Reporting group title	Arm E: Ublituximab to Umbralisib (TGR-1202)
Reporting group description: Subjects in Arm D were crossed over to umbralisib monotherapy upon confirmation of progressive disease (PD) by the independent review committee (IRC) to receive umbralisib, 800 mg orally, once daily, through Cycles 1-24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.	

Primary: Overall Response Rate (ORR)

End point title	Overall Response Rate (ORR) ^[1]
End point description: The ORR was defined as the sum of the percentage of subjects who had complete response (CR) and partial response (PR) and was determined according to the Revised Criteria for Malignant Lymphoma (Cheson 2007). CR was defined as the disappearance of all evidence of disease, spleen &/or liver normal in size, disappearance of all nodules of disease, all lymph nodes and nodal masses in fluorodeoxyglucose (FDG) avid lymphomas regressed to normal size. PR was defined as the regression of measurable disease and no new sites of disease. Regression was $\geq 50\%$ decrease in sum of the products of diameters (SPD) of index lesions, with no unequivocal increase in size of other lymph nodes, liver, or spleen. Data for this endpoint was not collected or analysed as the study was terminated due to the sponsor's business decision.	
End point type	Primary
End point timeframe: Up to approximately 6 years	
Notes: [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: Data for this endpoint was not collected or analysed as the study was terminated due to the sponsor's business decision.	

End point values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine	Arm D: Ublituximab Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[2]	0 ^[3]	0 ^[4]	0 ^[5]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[2] - Data was not collected or analysed due to the termination of the study by the sponsor.

[3] - Data was not collected or analysed due to the termination of the study by the sponsor.

[4] - Data was not collected or analysed due to the termination of the study by the sponsor.

[5] - Data was not collected or analysed due to the termination of the study by the sponsor.

End point values	Arm E: Ublituximab to Umbralisib (TGR-1202)			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[6]			
Units: percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[6] - Data was not collected or analysed due to the termination of the study by the sponsor.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)
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End point description:

PFS was defined as the interval from randomisation to the earlier of the first documentation of definitive disease progression or death from any cause. The appearance of any new lesion more than 1.5 centimeters (cm) in any axis, even if other lesions were decreasing in size was considered relapsed or progressive disease. At least a 50% increase from nadir in one of the following: SPD of index lesions, greatest transverse diameter (GTD) of any individual previously involved node, or GTD of any previously involved node provided that the GTD of that node was ≥ 1.5 cm. Data for this endpoint was not collected or analysed as the study was terminated due to the sponsor's business decision.

End point type	Secondary
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End point timeframe:

From date of randomisation until the date of first documented progression or death (up to approximately 6 years)

End point values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine	Arm D: Ublituximab Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[7]	0 ^[8]	0 ^[9]	0 ^[10]
Units: months				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

- [7] - Data was not collected or analysed due to the termination of the study by the sponsor.
 [8] - Data was not collected or analysed due to the termination of the study by the sponsor.
 [9] - Data was not collected or analysed due to the termination of the study by the sponsor.
 [10] - Data was not collected or analysed due to the termination of the study by the sponsor.

End point values	Arm E: Ublituximab to Umbralisib (TGR-1202)			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[11]			
Units: months				
number (confidence interval 95%)	(to)			

Notes:

- [11] - Data was not collected or analysed due to the termination of the study by the sponsor.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) at Month 6

End point title	Progression-Free Survival (PFS) at Month 6
End point description:	
PFS was defined as the percentage of subjects not experiencing progression i.e definitive disease progression or death from any cause by Month 6. The appearance of any new lesion more than 1.5 cm in any axis, even if other lesions were decreasing in size was considered relapsed or progressive disease. At least a 50% increase from nadir in one of the following: SPD of index lesions, GTD of any individual previously involved node, or GTD of any previously involved node provided that the GTD of that node was ≥ 1.5 cm. Data for this endpoint was not collected or analysed as the study was terminated due to the sponsor's business decision.	
End point type	Secondary
End point timeframe:	
At Month 6	

End point values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine	Arm D: Ublituximab Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[12]	0 ^[13]	0 ^[14]	0 ^[15]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

- [12] - Data was not collected or analysed due to the termination of the study by the sponsor.
 [13] - Data was not collected or analysed due to the termination of the study by the sponsor.
 [14] - Data was not collected or analysed due to the termination of the study by the sponsor.
 [15] - Data was not collected or analysed due to the termination of the study by the sponsor.

End point values	Arm E: Ublituximab to Umbralisib			
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	(TGR-1202)			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[16]			
Units: percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[16] - Data was not collected or analysed due to the termination of the study by the sponsor.

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response (CR) Rate

End point title	Complete Response (CR) Rate
End point description:	
CR rate is defined as the percentage of subjects who achieve a CR as determined according to the Revised Criteria for Malignant Lymphoma (Cheson 2007). CR was defined as the disappearance of all evidence of disease, spleen &/or liver normal in size, disappearance of all nodules of disease, all lymph nodes and nodal masses in FDG-avid lymphomas regressed to normal size. Data for this endpoint was not collected or analysed as the study was terminated due to the sponsor's business decision.	
End point type	Secondary
End point timeframe:	
Up to approximately 6 years	

End point values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine	Arm D: Ublituximab Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[17]	0 ^[18]	0 ^[19]	0 ^[20]
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[17] - Data was not collected or analysed due to the termination of the study by the sponsor.

[18] - Data was not collected or analysed due to the termination of the study by the sponsor.

[19] - Data was not collected or analysed due to the termination of the study by the sponsor.

[20] - Data was not collected or analysed due to the termination of the study by the sponsor.

End point values	Arm E: Ublituximab to Umbralisib (TGR-1202)			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[21]			
Units: percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[21] - Data was not collected or analysed due to the termination of the study by the sponsor.

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

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

OS is defined as the interval from randomisation to death from any cause. Data for this endpoint was not collected or analysed as the study was terminated due to the sponsor's business decision.

End point type	Secondary
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End point timeframe:

Up to approximately 6 years

End point values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine	Arm D: Ublituximab Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[22]	0 ^[23]	0 ^[24]	0 ^[25]
Units: months				
number (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[22] - Data was not collected or analysed due to the termination of the study by the sponsor.

[23] - Data was not collected or analysed due to the termination of the study by the sponsor.

[24] - Data was not collected or analysed due to the termination of the study by the sponsor.

[25] - Data was not collected or analysed due to the termination of the study by the sponsor.

End point values	Arm E: Ublituximab to Umbralisib (TGR-1202)			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[26]			
Units: months				
number (confidence interval 95%)	(to)			

Notes:

[26] - Data was not collected or analysed due to the termination of the study by the sponsor.

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)
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End point description:

DOR is defined as the interval from the first documentation of CR or PR to the earlier of the first documentation of definitive disease progression or death from any cause. CR=disappearance of all evidence of disease, spleen &/or liver normal in size, disappearance of all nodules of disease, all lymph nodes and nodal masses in FDG-avid lymphomas regressed to normal size. PR=regression of measurable disease and no new sites of disease. Regression= $\geq 50\%$ decrease in SPD of index lesions, with no unequivocal increase in size of other lymph nodes, liver, or spleen. PD=appearance of any new lesion

more than 1.5 cm in any axis, even if other lesions were decreasing in size. At least a 50% increase from nadir in one of the following: SPD of index lesions, GTD of any individual previously involved node, or GTD of any previously involved node provided that the GTD of that node was ≥ 1.5 cm. Data for this endpoint was not collected/analysed as the study was terminated due to the sponsor's decision.

End point type	Secondary
End point timeframe:	
Up to approximately 6 years	

End point values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine	Arm D: Ublituximab Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[27]	0 ^[28]	0 ^[29]	0 ^[30]
Units: months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[27] - Data was not collected or analysed due to the termination of the study by the sponsor.

[28] - Data was not collected or analysed due to the termination of the study by the sponsor.

[29] - Data was not collected or analysed due to the termination of the study by the sponsor.

[30] - Data was not collected or analysed due to the termination of the study by the sponsor.

End point values	Arm E: Ublituximab to Umbralisib (TGR-1202)			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[31]			
Units: months				
median (full range (min-max))	(to)			

Notes:

[31] - Data was not collected or analysed due to the termination of the study by the sponsor.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Subjects With Treatment Emergent Adverse Events (TEAEs)
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End point description:

An adverse event (AE) is any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product. An AE does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporarily associated with the use of a medicinal product, whether or not considered related to the medicinal product. TEAE is any AE that occur after first dosing of study medication and through the end of the study or through 30 days after the last dose of study treatment, or is considered treatment-related regardless of the start date of the event, or is present before first dosing of study medication but worsens in intensity or the investigator subsequently considers treatment-related. Safety Population included all subjects who were enrolled and received at least one dose of the study drug.

End point type	Secondary
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End point timeframe:

Up to approximately 6 years

End point values	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine	Arm D: Ublituximab Monotherapy
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	262	307	130	24
Units: Subjects	255	303	127	21

End point values	Arm E: Ublituximab to Umbralisib (TGR-1202)			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Subjects	12			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From signing of informed consent until 30 days after last dose of study drug (up to approximately 6 years)

Adverse event reporting additional description:

Safety Population included all subjects who were enrolled and received at least one dose of the study drug.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Arm A: Ublituximab + Umbralisib (TGR-1202)
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Reporting group description:

Subjects with FL, MZL, MCL, and DLBCL received ublituximab, 900 mg, IV, infusion on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6, and thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg, orally, once daily, through Cycles 1-24 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.

Reporting group title	Arm B: Umbralisib (TGR-1202) Monotherapy
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Reporting group description:

Subjects with FL, SLL, MZL, MCL, and DLBCL received umbralisib 800 mg orally, once daily through Cycles 1-24 (1 cycle=28 days), or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.

Reporting group title	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
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Reporting group description:

Subjects with DLBCL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) in combination with umbralisib, 800 mg orally, once daily through Cycles 1-24 and bendamustine 90 mg/m², IV infusion, on Days 1 and 2 of Cycles 1-6 or until disease progression, unacceptable toxicity or withdrawal from the study for other reasons.

Reporting group title	Arm D: Ublituximab Monotherapy
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Reporting group description:

Subjects with FL received ublituximab 900 mg, IV infusion, on Days 1, 8, and 15 of Cycle 1, Day 1 of Cycles 2-6 and, thereafter on Day 1 of every 3 cycles, through Cycle 24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.

Reporting group title	Arm E: Ublituximab to Umbralisib (TGR-1202)
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Reporting group description:

Subjects in Arm D were crossed over to umbralisib monotherapy upon confirmation of PD by the IRC to receive umbralisib, 800 mg orally, once daily, through Cycles 1-24 (1 cycle=28 days) or until disease progression, unacceptable toxicity, or withdrawal from the study for other reasons.

Serious adverse events	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
Total subjects affected by serious adverse events			
subjects affected / exposed	108 / 262 (41.22%)	106 / 307 (34.53%)	63 / 130 (48.46%)
number of deaths (all causes)	73	54	88
number of deaths resulting from adverse events	3	2	2

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (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
Breast cancer recurrent			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal adenocarcinoma			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Infected neoplasm			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (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
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Anal cancer			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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

Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Lymphoma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Malignant melanoma in situ			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Embolism			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Circulatory collapse			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Orthostatic hypotension			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Alcohol detoxification			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Catheter placement			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Fluid replacement			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip arthroplasty			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (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
Death			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	1 / 1	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated hernia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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

Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (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
Pain			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	5 / 130 (3.85%)
occurrences causally related to treatment / all	1 / 1	1 / 4	4 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal fistula			
subjects affected / exposed ^[1]	1 / 105 (0.95%)	0 / 139 (0.00%)	0 / 52 (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
Penile pain			
subjects affected / exposed ^[2]	0 / 157 (0.00%)	1 / 168 (0.60%)	0 / 78 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	4 / 262 (1.53%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 4	0 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	3 / 262 (1.15%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 262 (0.38%)	4 / 307 (1.30%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 1	0 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	1 / 262 (0.38%)	4 / 307 (1.30%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	1 / 1	2 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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

Pulmonary oedema			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Acute respiratory failure			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (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
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (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
Blood bilirubin increased			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Transaminases increased			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Neutrophil count decreased			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	4 / 262 (1.53%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial injury			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (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
Hip fracture			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	3 / 130 (2.31%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Arthropod bite			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain contusion			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Contusion			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Femur fracture			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Splenic rupture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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 failure			

subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	2 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute left ventricular failure			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Acute myocardial infarction			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Aortic valve disease			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 2	0 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Tachycardia			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular failure			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Acute coronary syndrome			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (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
Cardiac tamponade			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Coronary artery disease			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Myocardial infarction			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress cardiomyopathy			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Seizure			
subjects affected / exposed	3 / 262 (1.15%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Hyporeflexia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Lethargy			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Dementia			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Presyncope			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	5 / 262 (1.91%)	3 / 307 (0.98%)	3 / 130 (2.31%)
occurrences causally related to treatment / all	4 / 5	3 / 3	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	2 / 2	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	1 / 262 (0.38%)	4 / 307 (1.30%)	5 / 130 (3.85%)
occurrences causally related to treatment / all	0 / 1	2 / 4	3 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Neutropenia			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agranulocytosis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Haemolytic anaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Eye disorders			
Diplopia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Visual impairment			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	4 / 4	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	4 / 262 (1.53%)	10 / 307 (3.26%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	2 / 4	10 / 12	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune colitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Bezoar			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Dysphagia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Gastric haemorrhage			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Gastric perforation			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Small intestinal obstruction			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	3 / 130 (2.31%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Large intestinal haemorrhage			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	6 / 130 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
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 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic vein thrombosis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Hepatitis acute			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein occlusion			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Photosensitivity reaction			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash pruritic			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Urticaria			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 262 (1.53%)	5 / 307 (1.63%)	3 / 130 (2.31%)
occurrences causally related to treatment / all	1 / 4	2 / 5	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Renal failure			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Haematuria			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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

Pathological fracture			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Neck pain			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising myositis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Muscular weakness			
subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	2 / 4	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
COVID-19			
subjects affected / exposed	13 / 262 (4.96%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 13	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	11 / 262 (4.20%)	10 / 307 (3.26%)	4 / 130 (3.08%)
occurrences causally related to treatment / all	3 / 14	6 / 11	2 / 5
deaths causally related to treatment / all	0 / 0	1 / 1	1 / 1
COVID-19 pneumonia			

subjects affected / exposed	9 / 262 (3.44%)	12 / 307 (3.91%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	2 / 9	2 / 12	1 / 2
deaths causally related to treatment / all	1 / 1	0 / 0	1 / 1
Sepsis			
subjects affected / exposed	7 / 262 (2.67%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 7	6 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Bacterial infection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopulmonary aspergillosis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Campylobacter infection			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Enterocolitis infectious			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Oesophageal candidiasis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Pneumonia bacterial			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Pseudomonas infection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Urinary tract infection			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	1 / 1	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Appendicitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis pneumococcal			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Cellulitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal infection			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Empyema			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Influenza			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Meningitis aseptic			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia legionella			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia serratia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Postoperative wound infection			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Streptococcal sepsis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Viral infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Metabolism and nutrition disorders			
Tumour lysis syndrome			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	1 / 262 (0.38%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 1	2 / 5	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Fluid overload			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (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
Hypercalcaemia			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tetany			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (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
Cachexia			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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
Hypophosphataemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (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

Serious adverse events	Arm D: Ublituximab Monotherapy	Arm E: Ublituximab to Umbralisib (TGR-1202)	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 24 (20.83%)	5 / 12 (41.67%)	
number of deaths (all causes)	2	2	
number of deaths resulting from adverse events	1	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer recurrent			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal adenocarcinoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected neoplasm			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine carcinoma of the skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal cancer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extranodal marginal zone B-cell lymphoma (MALT type)			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal neoplasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoma			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superficial spreading melanoma stage unspecified			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Alcohol detoxification			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter placement			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid replacement			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip arthroplasty			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated hernia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Vaginal fistula			
subjects affected / exposed ^[1]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Penile pain			
subjects affected / exposed ^[2]	0 / 16 (0.00%)	0 / 8 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary congestion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			

subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatinine increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Fall			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol poisoning			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod bite			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain contusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic rupture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular failure			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Seizure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyporeflexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			

subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Agranulocytosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune haemolytic anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Visual impairment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune colitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bezoar			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric perforation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal haemorrhage			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal stenosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			

subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Hepatic vein thrombosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein occlusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Photosensitivity reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash pruritic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intervertebral disc protrusion subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Necrotising myositis subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations COVID-19 subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis perforated			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopulmonary aspergillosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Campylobacter infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis infectious			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal candidiasis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia cytomegaloviral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia haemophilus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomonas infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis pneumococcal			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corneal infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Empyema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia bacteraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis aseptic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia legionella			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia serratia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal sepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Tumour lysis syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fluid overload			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tetany			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Arm A: Ublituximab + Umbralisib (TGR-1202)	Arm B: Umbralisib (TGR-1202) Monotherapy	Arm C: Ublituximab + Umbralisib (TGR-1202) + Bendamustine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	254 / 262 (96.95%)	303 / 307 (98.70%)	125 / 130 (96.15%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	5 / 262 (1.91%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	6	1	0
Lipoma			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	2	2	0
Benign neoplasm of eye			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Bowen's disease			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Central nervous system lymphoma			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Haemangioma of skin			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Meningioma			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Neoplasm skin			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic keratosis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Skin cancer			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Squamous cell carcinoma of head and neck			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Tumour pain			
subjects affected / exposed	1 / 262 (0.38%)	4 / 307 (1.30%)	3 / 130 (2.31%)
occurrences (all)	1	4	4
Cancer pain			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	0	0	2
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Haemangioma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Neoplasm			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Oral neoplasm			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Skin neoplasm bleeding			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0

Squamous cell carcinoma subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Squamous cell carcinoma of skin subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	20 / 262 (7.63%) 29	23 / 307 (7.49%) 34	2 / 130 (1.54%) 2
Flushing subjects affected / exposed occurrences (all)	10 / 262 (3.82%) 11	4 / 307 (1.30%) 4	2 / 130 (1.54%) 2
Hypotension subjects affected / exposed occurrences (all)	7 / 262 (2.67%) 7	10 / 307 (3.26%) 12	13 / 130 (10.00%) 19
Hot flush subjects affected / exposed occurrences (all)	5 / 262 (1.91%) 5	18 / 307 (5.86%) 19	1 / 130 (0.77%) 1
Deep vein thrombosis subjects affected / exposed occurrences (all)	2 / 262 (0.76%) 2	2 / 307 (0.65%) 2	2 / 130 (1.54%) 2
Haematoma subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 2	2 / 307 (0.65%) 2	0 / 130 (0.00%) 0
Lymphoedema subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Thrombophlebitis superficial subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	2 / 130 (1.54%) 2
Arterial thrombosis subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Embolism			

subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	0	3	1
Embolism venous			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Haemorrhage			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hyperaemia			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Pallor			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Peripheral coldness			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Peripheral venous disease			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Subgaleal haematoma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Varicose vein			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Vascular insufficiency			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Vasculitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
Skin neoplasm excision			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	4	0	0

Hip arthroplasty			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Tooth extraction			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Cancer surgery			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Cataract operation			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Cerumen removal			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Knee arthroplasty			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	80 / 262 (30.53%)	96 / 307 (31.27%)	49 / 130 (37.69%)
occurrences (all)	109	133	71
Oedema peripheral			
subjects affected / exposed	35 / 262 (13.36%)	35 / 307 (11.40%)	15 / 130 (11.54%)
occurrences (all)	43	51	19
Pyrexia			
subjects affected / exposed	32 / 262 (12.21%)	37 / 307 (12.05%)	17 / 130 (13.08%)
occurrences (all)	37	63	29
Asthenia			
subjects affected / exposed	25 / 262 (9.54%)	29 / 307 (9.45%)	14 / 130 (10.77%)
occurrences (all)	30	37	20
Chills			
subjects affected / exposed	23 / 262 (8.78%)	22 / 307 (7.17%)	6 / 130 (4.62%)
occurrences (all)	32	27	6
Non-cardiac chest pain			

subjects affected / exposed	9 / 262 (3.44%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	9	6	1
Pain			
subjects affected / exposed	9 / 262 (3.44%)	7 / 307 (2.28%)	6 / 130 (4.62%)
occurrences (all)	9	7	6
Chest discomfort			
subjects affected / exposed	6 / 262 (2.29%)	3 / 307 (0.98%)	3 / 130 (2.31%)
occurrences (all)	6	4	3
Peripheral swelling			
subjects affected / exposed	6 / 262 (2.29%)	10 / 307 (3.26%)	4 / 130 (3.08%)
occurrences (all)	8	11	4
Feeling abnormal			
subjects affected / exposed	4 / 262 (1.53%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	4	5	0
Influenza like illness			
subjects affected / exposed	4 / 262 (1.53%)	4 / 307 (1.30%)	3 / 130 (2.31%)
occurrences (all)	5	4	3
Swelling			
subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	4	3	0
Catheter site pain			
subjects affected / exposed	3 / 262 (1.15%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	3	2	0
Chest pain			
subjects affected / exposed	3 / 262 (1.15%)	8 / 307 (2.61%)	2 / 130 (1.54%)
occurrences (all)	3	8	3
Face oedema			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	2	2	2
Feeling hot			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Gait disturbance			
subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	2 / 130 (1.54%)
occurrences (all)	2	3	2
Localised oedema			

subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	2	3	1
Malaise			
subjects affected / exposed	2 / 262 (0.76%)	7 / 307 (2.28%)	0 / 130 (0.00%)
occurrences (all)	3	8	0
Swelling face			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Administration site extravasation			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Adverse drug reaction			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Catheter site swelling			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Discomfort			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Early satiety			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Facial pain			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Feeling jittery			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	2	1
Illness			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Injection site bruising			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	1	2	1
Oedema			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Performance status decreased			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Disease progression			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Drug intolerance			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Exercise tolerance decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Feeling cold			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Generalised oedema			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Mass			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Mucosal hyperaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Nodule			

subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Sensation of foreign body			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Temperature intolerance			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Tenderness			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Thirst			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Tissue infiltration			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	5 / 262 (1.91%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	6	0	2
Seasonal allergy			
subjects affected / exposed	3 / 262 (1.15%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	3	3	0
Drug hypersensitivity			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	4	4	0
Hypogammaglobulinaemia			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	2	2	1
Allergy to animal			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Contrast media allergy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Contrast media reaction subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Immunodeficiency subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Sarcoidosis subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Reproductive system and breast disorders			
Scrotal oedema subjects affected / exposed ^[3] occurrences (all)	2 / 157 (1.27%) 2	0 / 168 (0.00%) 0	0 / 78 (0.00%) 0
Oedema genital subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Vulvovaginal pain subjects affected / exposed ^[4] occurrences (all)	1 / 105 (0.95%) 2	0 / 139 (0.00%) 0	0 / 52 (0.00%) 0
Benign prostatic hyperplasia subjects affected / exposed ^[5] occurrences (all)	0 / 157 (0.00%) 0	2 / 168 (1.19%) 2	1 / 78 (1.28%) 1
Breast discolouration subjects affected / exposed ^[6] occurrences (all)	0 / 105 (0.00%) 0	1 / 139 (0.72%) 1	0 / 52 (0.00%) 0
Breast mass subjects affected / exposed ^[7] occurrences (all)	0 / 105 (0.00%) 0	0 / 139 (0.00%) 0	1 / 52 (1.92%) 1
Breast oedema subjects affected / exposed ^[8] occurrences (all)	0 / 105 (0.00%) 0	1 / 139 (0.72%) 1	0 / 52 (0.00%) 0
Breast pain			

subjects affected / exposed ^[9]	0 / 105 (0.00%)	2 / 139 (1.44%)	1 / 52 (1.92%)
occurrences (all)	0	2	1
Breast swelling			
subjects affected / exposed ^[10]	0 / 105 (0.00%)	1 / 139 (0.72%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Genital lesion			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Genital rash			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Gynaecomastia			
subjects affected / exposed ^[11]	0 / 105 (0.00%)	1 / 139 (0.72%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Menstruation irregular			
subjects affected / exposed ^[12]	0 / 105 (0.00%)	0 / 139 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Orchitis noninfective			
subjects affected / exposed ^[13]	0 / 157 (0.00%)	1 / 168 (0.60%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Peyronie's disease			
subjects affected / exposed ^[14]	0 / 157 (0.00%)	0 / 168 (0.00%)	1 / 78 (1.28%)
occurrences (all)	0	0	1
Testicular oedema			
subjects affected / exposed ^[15]	0 / 157 (0.00%)	1 / 168 (0.60%)	0 / 78 (0.00%)
occurrences (all)	0	1	0
Testicular pain			
subjects affected / exposed ^[16]	0 / 157 (0.00%)	1 / 168 (0.60%)	1 / 78 (1.28%)
occurrences (all)	0	1	1
Vaginal haemorrhage			
subjects affected / exposed ^[17]	0 / 105 (0.00%)	0 / 139 (0.00%)	2 / 52 (3.85%)
occurrences (all)	0	0	2
Vulvovaginal dryness			
subjects affected / exposed ^[18]	0 / 105 (0.00%)	0 / 139 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Vulvovaginal pruritus			

subjects affected / exposed ^[19] occurrences (all)	0 / 105 (0.00%) 0	0 / 139 (0.00%) 0	1 / 52 (1.92%) 1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	41 / 262 (15.65%)	33 / 307 (10.75%)	18 / 130 (13.85%)
occurrences (all)	48	37	23
Cough			
subjects affected / exposed	32 / 262 (12.21%)	57 / 307 (18.57%)	17 / 130 (13.08%)
occurrences (all)	46	78	26
Oropharyngeal pain			
subjects affected / exposed	10 / 262 (3.82%)	13 / 307 (4.23%)	5 / 130 (3.85%)
occurrences (all)	10	13	5
Pleural effusion			
subjects affected / exposed	7 / 262 (2.67%)	11 / 307 (3.58%)	2 / 130 (1.54%)
occurrences (all)	7	13	17
Productive cough			
subjects affected / exposed	7 / 262 (2.67%)	9 / 307 (2.93%)	2 / 130 (1.54%)
occurrences (all)	8	11	2
Dysphonia			
subjects affected / exposed	6 / 262 (2.29%)	4 / 307 (1.30%)	1 / 130 (0.77%)
occurrences (all)	6	4	1
Nasal congestion			
subjects affected / exposed	5 / 262 (1.91%)	9 / 307 (2.93%)	3 / 130 (2.31%)
occurrences (all)	5	11	3
Chronic obstructive pulmonary disease			
subjects affected / exposed	4 / 262 (1.53%)	0 / 307 (0.00%)	3 / 130 (2.31%)
occurrences (all)	4	0	3
Epistaxis			
subjects affected / exposed	3 / 262 (1.15%)	7 / 307 (2.28%)	3 / 130 (2.31%)
occurrences (all)	7	7	3
Hypoxia			
subjects affected / exposed	3 / 262 (1.15%)	6 / 307 (1.95%)	2 / 130 (1.54%)
occurrences (all)	3	6	2
Pulmonary oedema			

subjects affected / exposed	3 / 262 (1.15%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	3	1	0
Respiratory tract congestion			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	3	0	0
Rhinitis allergic			
subjects affected / exposed	3 / 262 (1.15%)	4 / 307 (1.30%)	3 / 130 (2.31%)
occurrences (all)	3	5	3
Upper-airway cough syndrome			
subjects affected / exposed	3 / 262 (1.15%)	5 / 307 (1.63%)	2 / 130 (1.54%)
occurrences (all)	3	5	2
Wheezing			
subjects affected / exposed	3 / 262 (1.15%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences (all)	3	4	0
Dyspnoea exertional			
subjects affected / exposed	2 / 262 (0.76%)	6 / 307 (1.95%)	4 / 130 (3.08%)
occurrences (all)	2	6	6
Haemoptysis			
subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	2	3	1
Hiccups			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Rhinorrhoea			
subjects affected / exposed	2 / 262 (0.76%)	5 / 307 (1.63%)	4 / 130 (3.08%)
occurrences (all)	3	5	5
Throat irritation			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	2	0	1
Atelectasis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Dry throat			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Interstitial lung disease			

subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	2	4	0
Nasal obstruction			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	3	0	0
Nasal pruritus			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Nasal ulcer			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal swelling			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Paranasal sinus discomfort			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Pleurisy			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	1 / 262 (0.38%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	1	5	1
Pulmonary embolism			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Pulmonary hypertension			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Pulmonary mass			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Rales			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	4	0
Sinus congestion			

subjects affected / exposed	1 / 262 (0.38%)	7 / 307 (2.28%)	1 / 130 (0.77%)
occurrences (all)	1	7	1
Sinus pain			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	3	0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	3	0
Throat tightness			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Acute respiratory failure			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	0	2	1
Aspiration			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Bronchial obstruction			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Catarrh			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Laryngeal inflammation			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Mediastinal shift			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Nasal dryness			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Nasal mucosal ulcer			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Nasal oedema			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Nasal polyps			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Nasal septum disorder			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Paranasal sinus hypersecretion			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Pharyngeal erythema			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pharyngeal hypertrophy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pleuritic pain			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pneumothorax			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	2	1
Respiration abnormal			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Respiratory tract inflammation			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Rhinalgia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Rhonchi			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Snoring			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Sputum increased			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Vasomotor rhinitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	28 / 262 (10.69%)	40 / 307 (13.03%)	19 / 130 (14.62%)
occurrences (all)	33	45	25
Anxiety			
subjects affected / exposed	14 / 262 (5.34%)	8 / 307 (2.61%)	7 / 130 (5.38%)
occurrences (all)	15	9	7
Agitation			
subjects affected / exposed	6 / 262 (2.29%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	6	2	2
Confusional state			
subjects affected / exposed	6 / 262 (2.29%)	16 / 307 (5.21%)	1 / 130 (0.77%)
occurrences (all)	6	16	1
Depression			
subjects affected / exposed	5 / 262 (1.91%)	13 / 307 (4.23%)	4 / 130 (3.08%)
occurrences (all)	5	13	4
Restlessness			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences (all)	2	1	2

Sleep disorder			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	2	2	0
Delirium			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	4	0
Euphoric mood			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Irritability			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Mood swings			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Nightmare			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Poor quality sleep			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Abnormal dreams			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Affect lability			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Bruxism			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Disorientation			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Emotional disorder			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Mania			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Mental status changes			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	0	2	1
Mood altered			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Nervousness			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Panic attack			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Self-induced vomiting			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Product issues			
Device leakage			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Device breakage			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Device occlusion			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	2
Thrombosis in device			

subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Hepatic necrosis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Hepatitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Hepatocellular injury			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	3	0	0
Bile duct obstruction			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Cholecystitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gallbladder polyp			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hepatic cirrhosis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Hepatic steatosis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hepatitis acute			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0

Liver disorder subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	40 / 262 (15.27%) 80	51 / 307 (16.61%) 81	14 / 130 (10.77%) 23
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	38 / 262 (14.50%) 96	53 / 307 (17.26%) 107	13 / 130 (10.00%) 20
Neutrophil count decreased subjects affected / exposed occurrences (all)	23 / 262 (8.78%) 76	21 / 307 (6.84%) 33	17 / 130 (13.08%) 31
Blood creatinine increased subjects affected / exposed occurrences (all)	17 / 262 (6.49%) 29	38 / 307 (12.38%) 52	5 / 130 (3.85%) 6
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	14 / 262 (5.34%) 14	5 / 307 (1.63%) 5	6 / 130 (4.62%) 7
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	12 / 262 (4.58%) 14	14 / 307 (4.56%) 20	9 / 130 (6.92%) 14
Weight decreased subjects affected / exposed occurrences (all)	12 / 262 (4.58%) 15	24 / 307 (7.82%) 32	14 / 130 (10.77%) 19
Blood bilirubin increased subjects affected / exposed occurrences (all)	9 / 262 (3.44%) 16	8 / 307 (2.61%) 14	5 / 130 (3.85%) 9
Platelet count decreased subjects affected / exposed occurrences (all)	9 / 262 (3.44%) 17	16 / 307 (5.21%) 28	12 / 130 (9.23%) 27
White blood cell count decreased subjects affected / exposed occurrences (all)	9 / 262 (3.44%) 16	7 / 307 (2.28%) 10	9 / 130 (6.92%) 25
Weight increased			

subjects affected / exposed	7 / 262 (2.67%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	7	9	7
Lymphocyte count decreased			
subjects affected / exposed	4 / 262 (1.53%)	6 / 307 (1.95%)	3 / 130 (2.31%)
occurrences (all)	9	8	5
Blood magnesium decreased			
subjects affected / exposed	3 / 262 (1.15%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	3	1	0
Blood pressure increased			
subjects affected / exposed	3 / 262 (1.15%)	4 / 307 (1.30%)	2 / 130 (1.54%)
occurrences (all)	4	5	3
C-reactive protein increased			
subjects affected / exposed	3 / 262 (1.15%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	3	2	0
Hepatic enzyme increased			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	5	0	0
Blood uric acid increased			
subjects affected / exposed	2 / 262 (0.76%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences (all)	2	4	0
Ejection fraction decreased			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	2	1	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	3	2	0
Glomerular filtration rate			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	2	1	1
Ammonia increased			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Blood albumin decreased			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0

Blood bicarbonate decreased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Blood calcium increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Blood cholesterol increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	3 / 307 (0.98%) 3	1 / 130 (0.77%) 1
Blood glucose increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Blood immunoglobulin G decreased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	1 / 307 (0.33%) 2	0 / 130 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	2 / 307 (0.65%) 2	0 / 130 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Cardiac murmur subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	3 / 307 (0.98%) 3	1 / 130 (0.77%) 1
Clostridium test positive subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Coronavirus test positive subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Cytomegalovirus test positive subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
ECG signs of myocardial ischaemia subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0

Electrocardiogram QT prolonged subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	2 / 307 (0.65%) 2	0 / 130 (0.00%) 0
Haemoglobin decreased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	1 / 307 (0.33%) 2	0 / 130 (0.00%) 0
Hepatic enzyme abnormal subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Immunoglobulins decreased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Liver function test increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Magnetic resonance imaging brain abnormal subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Prostatic specific antigen increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Prothrombin time prolonged subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Red blood cell sedimentation rate increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Transaminases increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	3 / 307 (0.98%) 4	1 / 130 (0.77%) 1
Troponin increased subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Urinary sediment present			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 decreased			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Beta globulin decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	2
Blood immunoglobulin A decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blood immunoglobulin M increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blood iron decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blood potassium decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blood prolactin increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blood testosterone decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blood viscosity increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Body temperature decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	4	0

Body temperature increased subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	1 / 130 (0.77%) 1
Bone density decreased subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Breath sounds abnormal subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Faecal calprotectin increased subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Haemoglobin increased subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Haemophilus test positive subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Heart rate increased subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	0 / 307 (0.00%) 0	1 / 130 (0.77%) 1
Human rhinovirus positive subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	0 / 307 (0.00%) 0	1 / 130 (0.77%) 1
Immature granulocyte count increased subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Immunoglobulins increased subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
International normalised ratio increased			

subjects affected / exposed	0 / 262 (0.00%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences (all)	0	7	0
Light chain analysis decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Light chain analysis increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	2	3
Low density lipoprotein increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count abnormal			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Lymphocyte count increased			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Monocyte count decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Neutrophil count increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pedal pulse decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Platelet count increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Protein total decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Protein urine present			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Red cell distribution width increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Serum ferritin decreased			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Troponin I increased			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Vitamin D decreased			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	0	0	2
White blood cell count increased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	30 / 262 (11.45%)	2 / 307 (0.65%)	4 / 130 (3.08%)
occurrences (all)	35	2	5
Fall			
subjects affected / exposed	15 / 262 (5.73%)	17 / 307 (5.54%)	11 / 130 (8.46%)
occurrences (all)	16	19	12
Skin laceration			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	3	0	2
Limb injury			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Procedural pain			

subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	2	2	0
Accidental overdose			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Arthropod bite			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	3	0
Arthropod sting			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Lumbar vertebral fracture			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Radius fracture			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Rib fracture			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Skin abrasion			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	1	2	2
Thoracic vertebral fracture			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Traumatic intracranial haematoma			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Wound secretion			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Ankle fracture			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Compression fracture			

subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Concussion			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0
Foreign body in ear			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hand fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Head injury			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Hip fracture			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	0	0	2
Joint injury			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Lip injury			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Meniscus injury			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Muscle strain			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Overdose			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Periorbital haematoma			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Procedural hypotension			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Product administration error			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Skin injury			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Spinal fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Splenic injury			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Stress fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Subdural haematoma			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Tendon rupture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Thermal burn			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Tibia fracture			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Wound complication			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Congenital, familial and genetic			

disorders			
Phimosis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	9 / 262 (3.44%)	8 / 307 (2.61%)	7 / 130 (5.38%)
occurrences (all)	10	8	7
Atrial fibrillation			
subjects affected / exposed	4 / 262 (1.53%)	5 / 307 (1.63%)	5 / 130 (3.85%)
occurrences (all)	7	6	5
Palpitations			
subjects affected / exposed	4 / 262 (1.53%)	4 / 307 (1.30%)	5 / 130 (3.85%)
occurrences (all)	9	4	5
Angina pectoris			
subjects affected / exposed	3 / 262 (1.15%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	3	3	0
Cardiac failure			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Pericardial effusion			
subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	2	3	1
Sinus tachycardia			
subjects affected / exposed	2 / 262 (0.76%)	5 / 307 (1.63%)	2 / 130 (1.54%)
occurrences (all)	2	6	2
Atrial tachycardia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block complete			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Atrioventricular block second degree			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Cardiac failure congestive			

subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Cardiomyopathy			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Coronary artery disease			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Ventricular extrasystoles			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Aortic valve incompetence			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Arrhythmia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	0	0	2
Bradycardia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Cardiovascular insufficiency			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Extrasystoles			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Mitral valve incompetence			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pericarditis constrictive			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Supraventricular tachycardia			

subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	1 / 130 (0.77%) 1
Nervous system disorders			
Headache			
subjects affected / exposed	49 / 262 (18.70%)	50 / 307 (16.29%)	15 / 130 (11.54%)
occurrences (all)	67	81	18
Dizziness			
subjects affected / exposed	44 / 262 (16.79%)	51 / 307 (16.61%)	16 / 130 (12.31%)
occurrences (all)	50	63	21
Dysgeusia			
subjects affected / exposed	19 / 262 (7.25%)	27 / 307 (8.79%)	8 / 130 (6.15%)
occurrences (all)	19	29	10
Paraesthesia			
subjects affected / exposed	14 / 262 (5.34%)	10 / 307 (3.26%)	0 / 130 (0.00%)
occurrences (all)	20	15	0
Tremor			
subjects affected / exposed	13 / 262 (4.96%)	14 / 307 (4.56%)	9 / 130 (6.92%)
occurrences (all)	15	16	16
Neuropathy peripheral			
subjects affected / exposed	7 / 262 (2.67%)	7 / 307 (2.28%)	3 / 130 (2.31%)
occurrences (all)	7	7	3
Somnolence			
subjects affected / exposed	6 / 262 (2.29%)	8 / 307 (2.61%)	1 / 130 (0.77%)
occurrences (all)	6	10	1
Memory impairment			
subjects affected / exposed	5 / 262 (1.91%)	7 / 307 (2.28%)	2 / 130 (1.54%)
occurrences (all)	5	8	2
Peripheral sensory neuropathy			
subjects affected / exposed	5 / 262 (1.91%)	6 / 307 (1.95%)	6 / 130 (4.62%)
occurrences (all)	5	6	8
Syncope			
subjects affected / exposed	3 / 262 (1.15%)	5 / 307 (1.63%)	3 / 130 (2.31%)
occurrences (all)	3	5	4
Dysarthria			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0

Dyskinesia			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Hypoaesthesia			
subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	2	3	1
Lethargy			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	2	2	2
Taste disorder			
subjects affected / exposed	2 / 262 (0.76%)	7 / 307 (2.28%)	2 / 130 (1.54%)
occurrences (all)	2	7	2
Amnesia			
subjects affected / exposed	1 / 262 (0.38%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	1	6	1
Aphasia			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Balance disorder			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	1	2	3
Burning feet syndrome			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Carotid artery dissection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Disturbance in attention			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Dizziness postural			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Extrapyramidal disorder			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0

Facial paralysis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Loss of consciousness			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Muscle contractions involuntary			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	1	5	1
Notalgia paraesthetica			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Restless legs syndrome			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Seizure			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Ageusia			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Anosmia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Burning sensation			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0

Cervical radiculopathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	2	1
Cognitive disorder			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	0	2	1
Coordination abnormal			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Depressed level of consciousness			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Encephalopathy			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0
Haemorrhage intracranial			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Head discomfort			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hemiparesis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Hypogeusia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Intracranial aneurysm			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Lumbar radiculopathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Metabolic encephalopathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Nerve compression			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Parosmia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Polyneuropathy			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	0	0	2
Psychomotor hyperactivity			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Sciatica			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	0	4	0
Sensory loss			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Sinus headache			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Spinal cord compression			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Trigeminal neuralgia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Vascular headache			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	48 / 262 (18.32%)	28 / 307 (9.12%)	42 / 130 (32.31%)
occurrences (all)	88	70	113
Anaemia			
subjects affected / exposed	33 / 262 (12.60%)	33 / 307 (10.75%)	30 / 130 (23.08%)
occurrences (all)	46	59	71
Thrombocytopenia			
subjects affected / exposed	9 / 262 (3.44%)	16 / 307 (5.21%)	17 / 130 (13.08%)
occurrences (all)	24	39	39
Lymph node pain			
subjects affected / exposed	6 / 262 (2.29%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	6	1	0
Lymphopenia			
subjects affected / exposed	4 / 262 (1.53%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	5	0	3
Leukopenia			
subjects affected / exposed	3 / 262 (1.15%)	6 / 307 (1.95%)	9 / 130 (6.92%)
occurrences (all)	4	10	24
Febrile neutropenia			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences (all)	2	1	2
Lymphadenopathy			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	4 / 130 (3.08%)
occurrences (all)	2	1	4
Haemorrhagic diathesis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Normochromic anaemia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Blood loss anaemia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	0	0	2
Bone marrow failure			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences (all)	0	1	2
Leukocytosis			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	0	3	1
Lymphocytosis			
subjects affected / exposed	0 / 262 (0.00%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences (all)	0	8	0
Macrocytosis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Microcytic anaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pancytopenia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Paratracheal lymphadenopathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Splenic infarction			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	7 / 262 (2.67%)	9 / 307 (2.93%)	2 / 130 (1.54%)
occurrences (all)	7	10	2
Ear pain			
subjects affected / exposed	6 / 262 (2.29%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	7	5	1

Vertigo			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	3	1	1
Deafness			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	3	0
Ear congestion			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Ear pruritus			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Ear swelling			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
External ear inflammation			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Hypoacusis			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	1	3	1
Otorrhoea			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Vertigo positional			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Deafness unilateral			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Ear discomfort			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Ear disorder			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Excessive cerumen production subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Presbycusis subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Eye disorders			
Vision blurred subjects affected / exposed occurrences (all)	14 / 262 (5.34%) 15	12 / 307 (3.91%) 15	4 / 130 (3.08%) 5
Dry eye subjects affected / exposed occurrences (all)	5 / 262 (1.91%) 6	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Diplopia subjects affected / exposed occurrences (all)	3 / 262 (1.15%) 3	0 / 307 (0.00%) 0	0 / 130 (0.00%) 0
Lacrimation increased subjects affected / exposed occurrences (all)	3 / 262 (1.15%) 3	5 / 307 (1.63%) 6	1 / 130 (0.77%) 1
Eyelid ptosis subjects affected / exposed occurrences (all)	2 / 262 (0.76%) 3	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Vitreous floaters subjects affected / exposed occurrences (all)	2 / 262 (0.76%) 2	2 / 307 (0.65%) 2	1 / 130 (0.77%) 1
Cataract subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	1 / 307 (0.33%) 1	1 / 130 (0.77%) 1
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	1 / 307 (0.33%) 1	1 / 130 (0.77%) 1
Conjunctival hyperaemia subjects affected / exposed occurrences (all)	1 / 262 (0.38%) 1	2 / 307 (0.65%) 2	0 / 130 (0.00%) 0
Conjunctival oedema			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Erythema of eyelid			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Eye discharge			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Eye disorder			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Eye inflammation			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences (all)	1	1	2
Eye pruritus			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Eyelid oedema			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Ocular discomfort			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Retinal haemorrhage			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Visual acuity reduced			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Asthenopia			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Blepharitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Eye haemorrhage			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Eye swelling			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Glaucoma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hypermetropia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Mydriasis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Ocular hyperaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Photopsia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Retinal detachment			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Retinal tear			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Scleral hyperaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	2 / 130 (1.54%)
occurrences (all)	0	3	4
Xerophthalmia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	114 / 262 (43.51%)	163 / 307 (53.09%)	62 / 130 (47.69%)
occurrences (all)	252	372	96
Nausea			
subjects affected / exposed	104 / 262 (39.69%)	120 / 307 (39.09%)	56 / 130 (43.08%)
occurrences (all)	144	177	79
Vomiting			
subjects affected / exposed	39 / 262 (14.89%)	65 / 307 (21.17%)	35 / 130 (26.92%)
occurrences (all)	58	86	56
Constipation			
subjects affected / exposed	30 / 262 (11.45%)	29 / 307 (9.45%)	19 / 130 (14.62%)
occurrences (all)	32	37	21
Abdominal pain			
subjects affected / exposed	28 / 262 (10.69%)	37 / 307 (12.05%)	17 / 130 (13.08%)
occurrences (all)	37	51	18
Gastrooesophageal reflux disease			
subjects affected / exposed	17 / 262 (6.49%)	15 / 307 (4.89%)	4 / 130 (3.08%)
occurrences (all)	17	16	4
Dyspepsia			
subjects affected / exposed	12 / 262 (4.58%)	26 / 307 (8.47%)	15 / 130 (11.54%)
occurrences (all)	12	30	18
Abdominal pain upper			
subjects affected / exposed	10 / 262 (3.82%)	18 / 307 (5.86%)	1 / 130 (0.77%)
occurrences (all)	11	30	1

Colitis			
subjects affected / exposed	10 / 262 (3.82%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	14	6	1
Abdominal distension			
subjects affected / exposed	9 / 262 (3.44%)	20 / 307 (6.51%)	7 / 130 (5.38%)
occurrences (all)	10	21	8
Abdominal discomfort			
subjects affected / exposed	8 / 262 (3.05%)	7 / 307 (2.28%)	2 / 130 (1.54%)
occurrences (all)	9	7	3
Flatulence			
subjects affected / exposed	8 / 262 (3.05%)	14 / 307 (4.56%)	2 / 130 (1.54%)
occurrences (all)	9	15	3
Dry mouth			
subjects affected / exposed	6 / 262 (2.29%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	6	5	1
Dysphagia			
subjects affected / exposed	6 / 262 (2.29%)	7 / 307 (2.28%)	5 / 130 (3.85%)
occurrences (all)	7	8	5
Stomatitis			
subjects affected / exposed	6 / 262 (2.29%)	15 / 307 (4.89%)	7 / 130 (5.38%)
occurrences (all)	7	16	9
Anal incontinence			
subjects affected / exposed	5 / 262 (1.91%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	5	2	0
Haemorrhoids			
subjects affected / exposed	5 / 262 (1.91%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	5	2	2
Inguinal hernia			
subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	4	2	0
Oral pain			
subjects affected / exposed	4 / 262 (1.53%)	6 / 307 (1.95%)	2 / 130 (1.54%)
occurrences (all)	4	7	2
Abdominal pain lower			
subjects affected / exposed	3 / 262 (1.15%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	3	4	1

Ascites			
subjects affected / exposed	3 / 262 (1.15%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	5	2	3
Gastritis			
subjects affected / exposed	3 / 262 (1.15%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	3	3	0
Toothache			
subjects affected / exposed	3 / 262 (1.15%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences (all)	4	4	0
Eructation			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	2	2	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	2	2	2
Mouth ulceration			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	3 / 130 (2.31%)
occurrences (all)	2	0	3
Proctalgia			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	2	1	1
Salivary hypersecretion			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Abdominal hernia			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Abdominal rigidity			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Anal polyp			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Barrett's oesophagus			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1

Chapped lips			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Diverticulum			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Duodenitis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Enterocolitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	3	0	0
Epigastric discomfort			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	3 / 130 (2.31%)
occurrences (all)	1	1	3
Faeces discoloured			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal pain			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Gastrointestinal sounds abnormal			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Hiatus hernia			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	3	0
Large intestine polyp			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Leukoplakia oral			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0

Lip blister			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Mouth haemorrhage			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Oesophagitis			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Oral dysaesthesia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Oral mucosal eruption			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Pancreatitis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Parotid gland enlargement			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Proctitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Salivary gland pain			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Tongue coated			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Tongue disorder			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0

Umbilical hernia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Abdominal adhesions			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Abdominal mass			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Abdominal tenderness			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Abnormal faeces			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Apical granuloma			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Autoimmune enteropathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Breath odour			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Chronic gastritis			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Colitis microscopic			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Defaecation urgency			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Diverticulum intestinal			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Faecal vomiting			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Faeces soft			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	0	0	0
Frequent bowel movements			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gastric disorder			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gastric mucosa erythema			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gastric ulcer			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gastritis haemorrhagic			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal sphincter insufficiency			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gingival bleeding			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gingival pain			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Haematemesis			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Ileus			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Impaired gastric emptying			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Intra-abdominal haematoma			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Irritable bowel syndrome			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Large intestinal ulcer			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Lip exfoliation			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Neutropenic colitis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	4
Odynophagia			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Oedematous pancreatitis			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Oesophageal stenosis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Oral disorder			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Oral mucosal blistering			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Palatal disorder			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pancreatitis acute			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	0	4	0
Periodontal disease			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Poor dental condition			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Reflux gastritis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Stomatitis necrotising			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Tongue ulceration			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	0	4	0
Varices oesophageal			

subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	23 / 262 (8.78%)	27 / 307 (8.79%)	16 / 130 (12.31%)
occurrences (all)	24	30	21
Pruritus			
subjects affected / exposed	20 / 262 (7.63%)	14 / 307 (4.56%)	12 / 130 (9.23%)
occurrences (all)	24	19	16
Erythema			
subjects affected / exposed	9 / 262 (3.44%)	8 / 307 (2.61%)	3 / 130 (2.31%)
occurrences (all)	15	12	3
Alopecia			
subjects affected / exposed	8 / 262 (3.05%)	10 / 307 (3.26%)	0 / 130 (0.00%)
occurrences (all)	8	10	0
Hyperhidrosis			
subjects affected / exposed	8 / 262 (3.05%)	13 / 307 (4.23%)	2 / 130 (1.54%)
occurrences (all)	8	14	2
Night sweats			
subjects affected / exposed	8 / 262 (3.05%)	22 / 307 (7.17%)	5 / 130 (3.85%)
occurrences (all)	9	25	5
Rash maculo-papular			
subjects affected / exposed	8 / 262 (3.05%)	11 / 307 (3.58%)	9 / 130 (6.92%)
occurrences (all)	12	13	13
Dry skin			
subjects affected / exposed	7 / 262 (2.67%)	10 / 307 (3.26%)	5 / 130 (3.85%)
occurrences (all)	8	11	6
Rash pruritic			
subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	4 / 130 (3.08%)
occurrences (all)	7	2	4
Skin mass			
subjects affected / exposed	4 / 262 (1.53%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	4	3	0
Ecchymosis			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	4	0	1

Skin ulcer			
subjects affected / exposed	3 / 262 (1.15%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	3	3	2
Actinic keratosis			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	2	1	1
Dermatitis			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Pain of skin			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	2	0	1
Urticaria			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	3	4	0
Angioedema			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Blister			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Decubitus ulcer			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Dermatitis atopic			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Eczema asteatotic			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Exfoliative rash			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Hyperkeratosis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0

Hypersensitivity vasculitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Onychoclasia			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Psoriasis			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	8	0
Purpura			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Rash macular			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Rosacea			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Skin burning sensation			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Skin discolouration			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences (all)	1	1	2
Skin fissures			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Skin irritation			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	4	0	0
Skin lesion			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	1	2	2
Skin tightness			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0

Stasis dermatitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Cold sweat			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Dermal cyst			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Dermatitis acneiform			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Dermatitis bullous			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Drug eruption			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 262 (0.00%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences (all)	0	7	0
Erythema multiforme			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Nail discolouration			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Papule			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Purpura senile			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Scab			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Scar pain			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Skin atrophy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Skin discomfort			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 262 (0.00%)	4 / 307 (1.30%)	0 / 130 (0.00%)
occurrences (all)	0	6	0
Skin hypopigmentation			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Skin necrosis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Skin plaque			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Skin reaction			

subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Telangiectasia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	5 / 262 (1.91%)	5 / 307 (1.63%)	4 / 130 (3.08%)
occurrences (all)	5	5	4
Acute kidney injury			
subjects affected / exposed	4 / 262 (1.53%)	3 / 307 (0.98%)	7 / 130 (5.38%)
occurrences (all)	6	3	9
Haematuria			
subjects affected / exposed	4 / 262 (1.53%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	5	3	1
Dysuria			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	2 / 130 (1.54%)
occurrences (all)	4	0	2
Chronic kidney disease			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	2	3	1
Proteinuria			
subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	2	3	0
Calculus urinary			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Polyuria			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	1	2	0
Renal failure			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0

Strangury			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Ureteric stenosis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Urinary hesitation			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences (all)	1	1	2
Urinary tract obstruction			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Urine odour abnormal			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Azotaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Bladder discomfort			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Haemorrhage urinary tract			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Hydronephrosis			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Hypertonic bladder			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	0	2	1

Nephropathy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Nocturia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Renal pain			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Ureterolithiasis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 262 (0.00%)	4 / 307 (1.30%)	1 / 130 (0.77%)
occurrences (all)	0	5	1
Urinary tract pain			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Adrenal insufficiency			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Hyperparathyroidism			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hyperthyroidism			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal and connective tissue disorders			

Back pain			
subjects affected / exposed	32 / 262 (12.21%)	32 / 307 (10.42%)	11 / 130 (8.46%)
occurrences (all)	42	42	14
Arthralgia			
subjects affected / exposed	21 / 262 (8.02%)	34 / 307 (11.07%)	17 / 130 (13.08%)
occurrences (all)	48	47	18
Pain in extremity			
subjects affected / exposed	12 / 262 (4.58%)	25 / 307 (8.14%)	9 / 130 (6.92%)
occurrences (all)	12	32	10
Muscle spasms			
subjects affected / exposed	9 / 262 (3.44%)	19 / 307 (6.19%)	8 / 130 (6.15%)
occurrences (all)	14	23	8
Muscular weakness			
subjects affected / exposed	8 / 262 (3.05%)	16 / 307 (5.21%)	8 / 130 (6.15%)
occurrences (all)	8	20	9
Flank pain			
subjects affected / exposed	6 / 262 (2.29%)	11 / 307 (3.58%)	2 / 130 (1.54%)
occurrences (all)	8	12	2
Groin pain			
subjects affected / exposed	5 / 262 (1.91%)	10 / 307 (3.26%)	3 / 130 (2.31%)
occurrences (all)	5	10	3
Musculoskeletal pain			
subjects affected / exposed	5 / 262 (1.91%)	13 / 307 (4.23%)	3 / 130 (2.31%)
occurrences (all)	5	19	4
Joint swelling			
subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	4	2	0
Bone pain			
subjects affected / exposed	3 / 262 (1.15%)	4 / 307 (1.30%)	8 / 130 (6.15%)
occurrences (all)	4	7	8
Musculoskeletal discomfort			
subjects affected / exposed	3 / 262 (1.15%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	4	1	0
Arthritis			
subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	1 / 130 (0.77%)
occurrences (all)	2	4	1

Muscle tightness			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 262 (0.76%)	4 / 307 (1.30%)	2 / 130 (1.54%)
occurrences (all)	2	5	2
Osteoporosis			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Pain in jaw			
subjects affected / exposed	2 / 262 (0.76%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	3	3	0
Axillary mass			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Joint stiffness			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Osteoarthritis			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	1	2	1
Periarthritis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Psoriatic arthropathy			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Rheumatoid arthritis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0

Spinal osteoarthritis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	1 / 262 (0.38%)	6 / 307 (1.95%)	0 / 130 (0.00%)
occurrences (all)	2	12	0
Trigger finger			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Coccydynia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gouty arthritis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Joint range of motion decreased			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Limb discomfort			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Muscle fatigue			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Muscle twitching			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Rhabdomyolysis			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1

Synovial cyst subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	0 / 307 (0.00%) 0	1 / 130 (0.77%) 1
Tendon pain subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	0 / 307 (0.00%) 0	1 / 130 (0.77%) 1
Tendonitis subjects affected / exposed occurrences (all)	0 / 262 (0.00%) 0	1 / 307 (0.33%) 1	0 / 130 (0.00%) 0
Infections and infestations			
Urinary tract infection subjects affected / exposed occurrences (all)	17 / 262 (6.49%) 24	22 / 307 (7.17%) 27	11 / 130 (8.46%) 14
Pneumonia subjects affected / exposed occurrences (all)	12 / 262 (4.58%) 19	10 / 307 (3.26%) 11	5 / 130 (3.85%) 5
Upper respiratory tract infection subjects affected / exposed occurrences (all)	12 / 262 (4.58%) 15	42 / 307 (13.68%) 49	7 / 130 (5.38%) 10
COVID-19 subjects affected / exposed occurrences (all)	8 / 262 (3.05%) 8	9 / 307 (2.93%) 11	1 / 130 (0.77%) 1
Sinusitis subjects affected / exposed occurrences (all)	8 / 262 (3.05%) 8	8 / 307 (2.61%) 13	4 / 130 (3.08%) 5
Oral candidiasis subjects affected / exposed occurrences (all)	7 / 262 (2.67%) 10	2 / 307 (0.65%) 2	5 / 130 (3.85%) 5
Bronchitis subjects affected / exposed occurrences (all)	5 / 262 (1.91%) 6	5 / 307 (1.63%) 7	5 / 130 (3.85%) 10
Candida infection subjects affected / exposed occurrences (all)	5 / 262 (1.91%) 5	4 / 307 (1.30%) 4	1 / 130 (0.77%) 1
Nasopharyngitis			

subjects affected / exposed	5 / 262 (1.91%)	7 / 307 (2.28%)	2 / 130 (1.54%)
occurrences (all)	5	11	2
Respiratory tract infection			
subjects affected / exposed	5 / 262 (1.91%)	5 / 307 (1.63%)	0 / 130 (0.00%)
occurrences (all)	8	5	0
Cytomegalovirus infection reactivation			
subjects affected / exposed	4 / 262 (1.53%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	8	0	2
Cytomegalovirus infection			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	3	0	1
Folliculitis			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	4	0	0
Gastroenteritis			
subjects affected / exposed	3 / 262 (1.15%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	4	3	0
Influenza			
subjects affected / exposed	3 / 262 (1.15%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	3	7	1
Lower respiratory tract infection			
subjects affected / exposed	3 / 262 (1.15%)	8 / 307 (2.61%)	0 / 130 (0.00%)
occurrences (all)	3	9	0
Rhinitis			
subjects affected / exposed	3 / 262 (1.15%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	7	3	0
Sepsis			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	3	0	1
Cellulitis			
subjects affected / exposed	2 / 262 (0.76%)	4 / 307 (1.30%)	2 / 130 (1.54%)
occurrences (all)	2	7	3
Chronic sinusitis			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0

Conjunctivitis			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	2	1	1
Cystitis			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	3	1	1
Diverticulitis			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	3	0	1
Escherichia infection			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Herpes zoster			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	2	2	1
Oral herpes			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	3	2	1
Oral infection			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Pharyngitis			
subjects affected / exposed	2 / 262 (0.76%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	2	2	0
Skin infection			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Acute sinusitis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	2	1
Asymptomatic bacteriuria			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Bacteraemia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1

Bronchiolitis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Cellulitis of male external genital organ			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Clostridium difficile colitis			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	3 / 130 (2.31%)
occurrences (all)	1	3	4
Clostridium difficile infection			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Cytomegalovirus viraemia			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Enterocolitis infectious			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Epididymitis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Fungal infection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Gastric infection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal infection			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	1 / 262 (0.38%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	2	3	0
Latent tuberculosis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Molluscum contagiosum			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Nail infection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Nasal herpes			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Oesophageal candidiasis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Post procedural infection			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Proctitis herpes			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Pulpitis dental			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Scrotal infection			
subjects affected / exposed ^[20]	1 / 157 (0.64%)	0 / 168 (0.00%)	0 / 78 (0.00%)
occurrences (all)	1	0	0
Sialoadenitis			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Tinea cruris			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Tooth infection			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	4	0
Vaginal infection			
subjects affected / exposed ^[21]	1 / 105 (0.95%)	1 / 139 (0.72%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
Viral infection			
subjects affected / exposed	1 / 262 (0.38%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	1	3	0
Alpha haemolytic streptococcal infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Campylobacter infection			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Enterocolitis viral			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Erysipelas			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Fungal skin infection			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	2 / 130 (1.54%)
occurrences (all)	0	2	2
Gastroenteritis norovirus			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Gastroenteritis viral			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	1 / 130 (0.77%)
occurrences (all)	0	2	1
Gastrointestinal viral infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Helicobacter gastritis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Helicobacter infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Herpes simplex			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Herpes virus infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Infected cyst			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Kidney infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Localised infection			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Measles			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Moraxella infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0

Neutropenic sepsis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Onychomycosis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Ophthalmic herpes simplex			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Oral fungal infection			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Periorbital cellulitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Pulmonary mycosis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Septic shock			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Skin bacterial infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Splenic infection			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Staphylococcal sepsis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1

Tinea pedis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Tinea versicolour			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Viral pharyngitis			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 262 (0.00%)	4 / 307 (1.30%)	1 / 130 (0.77%)
occurrences (all)	0	4	1
Vulvovaginal mycotic infection			
subjects affected / exposed ^[22]	0 / 105 (0.00%)	0 / 139 (0.00%)	1 / 52 (1.92%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Contusion			
subjects affected / exposed	10 / 262 (3.82%)	10 / 307 (3.26%)	5 / 130 (3.85%)
occurrences (all)	15	11	6
Ligament sprain			
subjects affected / exposed	4 / 262 (1.53%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	4	2	0
Humerus fracture			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	38 / 262 (14.50%)	37 / 307 (12.05%)	25 / 130 (19.23%)
occurrences (all)	57	62	38
Decreased appetite			

subjects affected / exposed	37 / 262 (14.12%)	59 / 307 (19.22%)	32 / 130 (24.62%)
occurrences (all)	45	83	35
Hypomagnesaemia			
subjects affected / exposed	22 / 262 (8.40%)	20 / 307 (6.51%)	15 / 130 (11.54%)
occurrences (all)	31	26	22
Dehydration			
subjects affected / exposed	11 / 262 (4.20%)	18 / 307 (5.86%)	16 / 130 (12.31%)
occurrences (all)	13	20	20
Hypophosphataemia			
subjects affected / exposed	11 / 262 (4.20%)	12 / 307 (3.91%)	6 / 130 (4.62%)
occurrences (all)	13	22	15
Hyponatraemia			
subjects affected / exposed	8 / 262 (3.05%)	6 / 307 (1.95%)	7 / 130 (5.38%)
occurrences (all)	10	10	11
Hypercalcaemia			
subjects affected / exposed	5 / 262 (1.91%)	7 / 307 (2.28%)	3 / 130 (2.31%)
occurrences (all)	5	10	3
Hyperglycaemia			
subjects affected / exposed	5 / 262 (1.91%)	8 / 307 (2.61%)	4 / 130 (3.08%)
occurrences (all)	5	10	6
Hyperuricaemia			
subjects affected / exposed	5 / 262 (1.91%)	11 / 307 (3.58%)	7 / 130 (5.38%)
occurrences (all)	6	14	7
Hypocalcaemia			
subjects affected / exposed	4 / 262 (1.53%)	11 / 307 (3.58%)	5 / 130 (3.85%)
occurrences (all)	6	18	5
Hypercholesterolaemia			
subjects affected / exposed	3 / 262 (1.15%)	4 / 307 (1.30%)	2 / 130 (1.54%)
occurrences (all)	3	8	2
Hyperkalaemia			
subjects affected / exposed	3 / 262 (1.15%)	9 / 307 (2.93%)	0 / 130 (0.00%)
occurrences (all)	3	10	0
Tumour lysis syndrome			
subjects affected / exposed	3 / 262 (1.15%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	3	0	0
Vitamin D deficiency			

subjects affected / exposed	3 / 262 (1.15%)	5 / 307 (1.63%)	0 / 130 (0.00%)
occurrences (all)	3	5	0
Gout			
subjects affected / exposed	2 / 262 (0.76%)	5 / 307 (1.63%)	1 / 130 (0.77%)
occurrences (all)	2	5	1
Hyperlipidaemia			
subjects affected / exposed	2 / 262 (0.76%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	2	0	0
Hypertriglyceridaemia			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Hypoalbuminaemia			
subjects affected / exposed	2 / 262 (0.76%)	5 / 307 (1.63%)	2 / 130 (1.54%)
occurrences (all)	2	5	4
Hypoglycaemia			
subjects affected / exposed	2 / 262 (0.76%)	5 / 307 (1.63%)	0 / 130 (0.00%)
occurrences (all)	2	5	0
Increased appetite			
subjects affected / exposed	2 / 262 (0.76%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	2	1	0
Acidosis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Diabetes mellitus			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Fluid overload			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	1	0	1
Iron deficiency			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	1	1	1
Magnesium deficiency			

subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	2 / 130 (1.54%)
occurrences (all)	1	1	2
Metabolic acidosis			
subjects affected / exposed	1 / 262 (0.38%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	1	1	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 262 (0.38%)	0 / 307 (0.00%)	0 / 130 (0.00%)
occurrences (all)	1	0	0
Abnormal loss of weight			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Cachexia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Failure to thrive			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 262 (0.00%)	2 / 307 (0.65%)	0 / 130 (0.00%)
occurrences (all)	0	2	0
Hypernatraemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	1 / 130 (0.77%)
occurrences (all)	0	1	1
Hypochloraemia			
subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Hypoproteinaemia			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Obesity			

subjects affected / exposed	0 / 262 (0.00%)	0 / 307 (0.00%)	1 / 130 (0.77%)
occurrences (all)	0	0	1
Vitamin B12 deficiency			
subjects affected / exposed	0 / 262 (0.00%)	3 / 307 (0.98%)	0 / 130 (0.00%)
occurrences (all)	0	3	0
Zinc deficiency			
subjects affected / exposed	0 / 262 (0.00%)	1 / 307 (0.33%)	0 / 130 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	14 / 262 (5.34%)	24 / 307 (7.82%)	4 / 130 (3.08%)
occurrences (all)	15	29	6
Neck pain			
subjects affected / exposed	12 / 262 (4.58%)	5 / 307 (1.63%)	5 / 130 (3.85%)
occurrences (all)	13	5	5

Non-serious adverse events	Arm D: Ublituximab Monotherapy	Arm E: Ublituximab to Umbralisib (TGR- 1202)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 24 (83.33%)	12 / 12 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Lipoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Benign neoplasm of eye			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bowen's disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Central nervous system lymphoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Haemangioma of skin			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Meningioma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Neoplasm skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic keratosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin cancer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Squamous cell carcinoma of head and neck			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tumour pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cancer pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Haemangioma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Neoplasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Oral neoplasm			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Skin neoplasm bleeding subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 12 (8.33%) 1	
Squamous cell carcinoma subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 12 (0.00%) 0	
Squamous cell carcinoma of skin subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Vascular disorders			
Hypertension subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 5	0 / 12 (0.00%) 0	
Flushing subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 3	0 / 12 (0.00%) 0	
Hypotension subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Hot flush subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Deep vein thrombosis subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Haematoma subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 12 (8.33%) 1	
Lymphoedema subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Thrombophlebitis superficial subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Arterial thrombosis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Embolism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Embolism venous			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hyperaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pallor			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Peripheral coldness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Peripheral venous disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Subgaleal haematoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Varicose vein			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vascular insufficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vasculitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			

Skin neoplasm excision subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Hip arthroplasty subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Tooth extraction subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Cancer surgery subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Cataract operation subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Cerumen removal subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Knee arthroplasty subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	5 / 24 (20.83%) 5	3 / 12 (25.00%) 3	
Oedema peripheral subjects affected / exposed occurrences (all)	4 / 24 (16.67%) 5	2 / 12 (16.67%) 2	
Pyrexia subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 3	2 / 12 (16.67%) 2	
Asthenia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Chills			

subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)
occurrences (all)	3	0
Non-cardiac chest pain		
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)
occurrences (all)	2	0
Pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Chest discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Peripheral swelling		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Feeling abnormal		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Influenza like illness		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Swelling		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Catheter site pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Chest pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Face oedema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Feeling hot		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Gait disturbance		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Localised oedema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Malaise		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Swelling face		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Administration site extravasation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Adverse drug reaction		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Axillary pain		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Catheter site swelling		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Early satiety		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Facial pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Feeling jittery		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Illness		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Injection site bruising		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Mucosal inflammation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oedema		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Performance status decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Disease progression		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Drug intolerance		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Exercise tolerance decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Feeling cold		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
General physical health deterioration		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Generalised oedema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Mass		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Mucosal hyperaemia		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nodule			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sensation of foreign body			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Temperature intolerance			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tenderness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Thirst			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tissue infiltration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Seasonal allergy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Drug hypersensitivity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Allergy to animal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Contrast media allergy subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Contrast media reaction subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Immunodeficiency subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Sarcoidosis subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Reproductive system and breast disorders			
Scrotal oedema subjects affected / exposed ^[3] occurrences (all)	0 / 16 (0.00%) 0	0 / 8 (0.00%) 0	
Oedema genital subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Pelvic pain subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Vulvovaginal pain subjects affected / exposed ^[4] occurrences (all)	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0	
Benign prostatic hyperplasia subjects affected / exposed ^[5] occurrences (all)	0 / 16 (0.00%) 0	0 / 8 (0.00%) 0	
Breast discolouration subjects affected / exposed ^[6] occurrences (all)	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0	
Breast mass subjects affected / exposed ^[7] occurrences (all)	0 / 8 (0.00%) 0	0 / 4 (0.00%) 0	
Breast oedema			

subjects affected / exposed ^[8]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Breast pain			
subjects affected / exposed ^[9]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Breast swelling			
subjects affected / exposed ^[10]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Genital lesion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Genital rash			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gynaecomastia			
subjects affected / exposed ^[11]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Menstruation irregular			
subjects affected / exposed ^[12]	0 / 8 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Orchitis noninfective			
subjects affected / exposed ^[13]	0 / 16 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Peyronie's disease			
subjects affected / exposed ^[14]	0 / 16 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Testicular oedema			
subjects affected / exposed ^[15]	0 / 16 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Testicular pain			
subjects affected / exposed ^[16]	0 / 16 (0.00%)	0 / 8 (0.00%)	
occurrences (all)	0	0	
Vaginal haemorrhage			
subjects affected / exposed ^[17]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal dryness			

subjects affected / exposed ^[18]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal pruritus			
subjects affected / exposed ^[19]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Cough			
subjects affected / exposed	5 / 24 (20.83%)	2 / 12 (16.67%)	
occurrences (all)	8	2	
Oropharyngeal pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Pleural effusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hypoxia			

subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Pulmonary oedema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Respiratory tract congestion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rhinitis allergic		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Upper-airway cough syndrome		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Wheezing		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	2	0
Dyspnoea exertional		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Haemoptysis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hiccups		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rhinorrhoea		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Throat irritation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Atelectasis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dry throat		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Interstitial lung disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nasal obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nasal pruritus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nasal ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Paranasal sinus discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pleurisy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pneumonitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pulmonary embolism			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Pulmonary hypertension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pulmonary mass			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rales			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sinus pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Throat tightness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Acute respiratory failure			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Aspiration			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Asthma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bronchial hyperreactivity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bronchial obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Catarrh			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Laryngeal inflammation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Mediastinal shift			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nasal dryness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nasal mucosal ulcer		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nasal oedema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nasal polyps		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nasal septum disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Paranasal sinus hypersecretion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pharyngeal erythema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pharyngeal hypertrophy		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pleuritic pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pneumothorax		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Respiration abnormal		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Respiratory failure		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Respiratory tract inflammation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rhinalgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rhonchi			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Snoring			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sputum increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vasomotor rhinitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Anxiety			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Agitation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Confusional state			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	

Restlessness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Sleep disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Delirium		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Depressed mood		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Euphoric mood		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Irritability		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Mood swings		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nightmare		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Poor quality sleep		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abnormal dreams		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Affect lability		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Bruxism		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Disorientation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Emotional disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hallucination			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Mania			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Mental status changes			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Mood altered			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nervousness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Panic attack			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Self-induced vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Product issues			
Device leakage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Device breakage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Device occlusion			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Thrombosis in device			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hepatic necrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hepatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hepatocellular injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bile duct obstruction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cholecystitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gallbladder polyp			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hepatic steatosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hepatitis acute			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Liver disorder subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Investigations			
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	1 / 12 (8.33%) 4	
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	1 / 12 (8.33%) 7	
Neutrophil count decreased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 2	2 / 12 (16.67%) 6	
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 12 (8.33%) 1	
Blood lactate dehydrogenase increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Weight decreased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 12 (0.00%) 0	
Blood bilirubin increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Platelet count decreased subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 12 (0.00%) 0	
White blood cell count decreased			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Weight increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Lymphocyte count decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood magnesium decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood pressure increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
C-reactive protein increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hepatic enzyme increased		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Blood uric acid increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ejection fraction decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gamma-glutamyltransferase increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Glomerular filtration rate		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ammonia increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Blood albumin decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Blood bicarbonate decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Blood calcium increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Blood glucose increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Blood immunoglobulin G decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Blood urine present subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Cardiac murmur subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Clostridium test positive subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Coronavirus test positive subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0
Cytomegalovirus test positive subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0

ECG signs of myocardial ischaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Haemoglobin decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hepatic enzyme abnormal		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Immunoglobulins decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Liver function test increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Magnetic resonance imaging brain abnormal		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Prostatic specific antigen increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Prothrombin time prolonged		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Red blood cell sedimentation rate increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Transaminases increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Troponin increased		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Urinary sediment present		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Vitamin B12 decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Beta globulin decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood creatine phosphokinase increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood immunoglobulin A decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood immunoglobulin M increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood iron decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood potassium decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood prolactin increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood testosterone decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blood viscosity increased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Body temperature decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Body temperature increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Bone density decreased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Breath sounds abnormal subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Faecal calprotectin increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Haemoglobin increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Haemophilus test positive subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Heart rate increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Human rhinovirus positive subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Immature granulocyte count increased subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Immunoglobulins increased			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
International normalised ratio increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Light chain analysis decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Light chain analysis increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Low density lipoprotein increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count abnormal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Monocyte count decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Neutrophil count increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pedal pulse decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Platelet count increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Protein total decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Protein urine present			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Red cell distribution width increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Serum ferritin decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Troponin I increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vitamin D decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
White blood cell count increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	3 / 24 (12.50%)	0 / 12 (0.00%)	
occurrences (all)	5	0	
Fall			
subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Skin laceration			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Limb injury			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Procedural pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Accidental overdose		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Arthropod bite		
subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)
occurrences (all)	1	1
Arthropod sting		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Lumbar vertebral fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Radius fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rib fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin abrasion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Thoracic vertebral fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Traumatic intracranial haematoma		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Wound secretion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ankle fracture		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Compression fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Concussion			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Foreign body in ear			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hand fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Head injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hip fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Joint injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Lip injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Meniscus injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Muscle strain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Overdose			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Periorbital haematoma			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Procedural hypotension		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Product administration error		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin injury		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Spinal compression fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Spinal fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Splenic injury		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Stress fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Subdural haematoma		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Tendon rupture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Thermal burn		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Tibia fracture		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Wound complication		

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Congenital, familial and genetic disorders Phimosis subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Palpitations subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Angina pectoris subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Cardiac failure subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Pericardial effusion subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Atrial tachycardia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Atrioventricular block complete subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Atrioventricular block second degree			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cardiac failure congestive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cardiomyopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Coronary artery disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sinus bradycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ventricular extrasystoles			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Aortic valve incompetence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Arrhythmia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bradycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cardiovascular insufficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Extrasystoles			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Mitral valve incompetence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pericarditis constrictive			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Dizziness			
subjects affected / exposed	4 / 24 (16.67%)	3 / 12 (25.00%)	
occurrences (all)	4	3	
Dysgeusia			
subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Paraesthesia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Neuropathy peripheral			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Somnolence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Memory impairment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Dysarthria		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dyskinesia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypoaesthesia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Lethargy		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Taste disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Amnesia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Aphasia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Balance disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Burning feet syndrome		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Carotid artery dissection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Disturbance in attention		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Dizziness postural		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Extrapyramidal disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Facial paralysis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Loss of consciousness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Muscle contractions involuntary		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Neuralgia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Notalgia paraesthetica		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Presyncope		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Restless legs syndrome		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Seizure		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ageusia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Anosmia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Burning sensation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Carpal tunnel syndrome		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Cervical radiculopathy		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Cognitive disorder		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Coordination abnormal		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Depressed level of consciousness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Encephalopathy		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Haemorrhage intracranial		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Head discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hemiparesis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypogeusia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Intracranial aneurysm		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Lumbar radiculopathy		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Metabolic encephalopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nerve compression			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Parosmia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Peripheral motor neuropathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Polyneuropathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Post herpetic neuralgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Psychomotor hyperactivity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sensory loss			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sinus headache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Spinal cord compression			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Trigeminal neuralgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Vascular headache subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Blood and lymphatic system disorders			
Neutropenia subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 4	3 / 12 (25.00%) 7	
Anaemia subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 2	2 / 12 (16.67%) 6	
Thrombocytopenia subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	4 / 12 (33.33%) 5	
Lymph node pain subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	1 / 12 (8.33%) 1	
Lymphopenia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Leukopenia subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 12 (0.00%) 0	
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 12 (0.00%) 0	
Haemorrhagic diathesis subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Normochromic anaemia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	0 / 12 (0.00%) 0	
Blood loss anaemia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bone marrow failure			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Eosinophilia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Leukocytosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Lymphocytosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Macrocytosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Microcytic anaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pancytopenia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Paratracheal lymphadenopathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Splenic infarction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Ear pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Vertigo		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Deafness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ear congestion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ear pruritus		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ear swelling		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
External ear inflammation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypoacusis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Otorrhoea		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Vertigo positional		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Deafness unilateral		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ear discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Ear disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Excessive cerumen production			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Presbycusis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Dry eye			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Diplopia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Lacrimation increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eyelid ptosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vitreous floaters			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cataract			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Conjunctival haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Conjunctival hyperaemia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Conjunctival oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Erythema of eyelid			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye discharge			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye inflammation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye pruritus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eyelid oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ocular discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Periorbital oedema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Retinal haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Visual acuity reduced			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Asthenopia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Blepharitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis allergic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye irritation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Glaucoma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hypermetropia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Mydriasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Photopsia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Retinal detachment			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Retinal tear			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Scleral hyperaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Visual impairment			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Xerophthalmia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 24 (12.50%)	7 / 12 (58.33%)	
occurrences (all)	5	16	
Nausea			
subjects affected / exposed	2 / 24 (8.33%)	4 / 12 (33.33%)	
occurrences (all)	3	4	
Vomiting			
subjects affected / exposed	1 / 24 (4.17%)	3 / 12 (25.00%)	
occurrences (all)	1	3	
Constipation			
subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Abdominal pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Dyspepsia			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	
occurrences (all)	2	0	

Abdominal pain upper		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Colitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abdominal distension		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Abdominal discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Flatulence		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dry mouth		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dysphagia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Stomatitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Anal incontinence		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Haemorrhoids		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Inguinal hernia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oral pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Abdominal pain lower		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ascites		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gastritis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Toothache		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Eructation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Haemorrhoidal haemorrhage		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Mouth ulceration		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Proctalgia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Salivary hypersecretion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abdominal hernia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abdominal rigidity		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Anal polyp		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Barrett's oesophagus		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Chapped lips		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Diverticulum		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Duodenitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Enterocolitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Epigastric discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Faeces discoloured		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gastrointestinal pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gastrointestinal sounds abnormal		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Haematochezia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hiatus hernia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Large intestine polyp		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Leukoplakia oral		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Lip blister		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Mouth haemorrhage		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oesophagitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oral dysaesthesia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oral mucosal eruption		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pancreatitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Parotid gland enlargement		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Proctitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rectal haemorrhage		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Salivary gland pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Tongue coated		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Tongue disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Umbilical hernia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abdominal adhesions		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abdominal mass		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abdominal tenderness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abnormal faeces		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Aphthous ulcer		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Apical granuloma		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Autoimmune enteropathy		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Breath odour		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Chronic gastritis		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Colitis microscopic		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Defaecation urgency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Diverticulum intestinal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Faecal vomiting			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Faeces soft			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Frequent bowel movements			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastric disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastric mucosa erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastric ulcer			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastritis haemorrhagic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal sphincter insufficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gingival bleeding			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Gingival pain			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Haematemesis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypoaesthesia oral		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ileus		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Impaired gastric emptying		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Intra-abdominal haematoma		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Irritable bowel syndrome		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Large intestinal ulcer		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Lip exfoliation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Melaena		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Mesenteric vein thrombosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Neutropenic colitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Odynophagia		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oedematous pancreatitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oesophageal stenosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oral disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oral mucosal blistering		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Palatal disorder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pancreatitis acute		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Paraesthesia oral		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Periodontal disease		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Poor dental condition		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Reflux gastritis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Stomatitis necrotising		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Tongue ulceration		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Varices oesophageal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	3 / 24 (12.50%)	3 / 12 (25.00%)	
occurrences (all)	3	6	
Pruritus			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Hyperhidrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Rash maculo-papular			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rash pruritic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin mass			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Ecchymosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin ulcer		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Actinic keratosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dermatitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pain of skin		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Urticaria		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Angioedema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Blister		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Decubitus ulcer		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dermatitis atopic		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Eczema asteatotic		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Exfoliative rash		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Hyperkeratosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypersensitivity vasculitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Onychoclasia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Psoriasis		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Purpura		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rash macular		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rosacea		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin burning sensation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin discolouration		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin fissures		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin irritation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin lesion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Skin tightness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Stasis dermatitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Cold sweat		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dermal cyst		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dermatitis acneiform		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dermatitis bullous		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Dermatitis exfoliative generalised		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Drug eruption		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Eczema		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Erythema multiforme		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nail discolouration		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Palmar-plantar erythrodysaesthesia syndrome		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Papule			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Photosensitivity reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Purpura senile			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rash erythematous			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Scab			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Scar pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin atrophy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin exfoliation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin hypopigmentation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin necrosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin plaque			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Telangiectasia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Acute kidney injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Haematuria			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Dysuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Chronic kidney disease			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Calculus urinary			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Micturition urgency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Polyuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

Renal failure		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Strangury		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ureteric stenosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Urinary hesitation		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Urinary retention		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Urinary tract obstruction		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Urine odour abnormal		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Azotaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Bladder discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Haemorrhage urinary tract		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hydronephrosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypertonic bladder		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Nephrolithiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nephropathy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nocturia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Renal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ureterolithiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Urinary incontinence			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Urinary tract pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Adrenal insufficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hyperparathyroidism			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia of malignancy			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Hyperthyroidism			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	4 / 24 (16.67%)	1 / 12 (8.33%)	
occurrences (all)	6	1	
Arthralgia			
subjects affected / exposed	3 / 24 (12.50%)	0 / 12 (0.00%)	
occurrences (all)	3	0	
Pain in extremity			
subjects affected / exposed	3 / 24 (12.50%)	1 / 12 (8.33%)	
occurrences (all)	4	1	
Muscle spasms			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Muscular weakness			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Flank pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	2 / 24 (8.33%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
Musculoskeletal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Joint swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bone pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal discomfort			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Arthritis		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Muscle tightness		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Musculoskeletal chest pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Osteoporosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pain in jaw		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Axillary mass		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Intervertebral disc protrusion		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Joint stiffness		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Osteoarthritis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Periarthritis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Psoriatic arthropathy		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rheumatoid arthritis		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Rotator cuff syndrome		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Spinal osteoarthritis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Spinal pain		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Trigger finger		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Bursitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Coccydynia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gouty arthritis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Joint range of motion decreased		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Limb discomfort		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Muscle fatigue		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Muscle twitching		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Musculoskeletal stiffness		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rhabdomyolysis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Synovial cyst			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tendon pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tendonitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 24 (16.67%)	1 / 12 (8.33%)	
occurrences (all)	4	1	
COVID-19			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	2 / 24 (8.33%)	2 / 12 (16.67%)	
occurrences (all)	2	3	
Oral candidiasis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	

Candida infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cytomegalovirus infection reactivation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Folliculitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Sepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cellulitis			

subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Chronic sinusitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Conjunctivitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Cystitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Diverticulitis		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Escherichia infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Herpes zoster		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oral herpes		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oral infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pharyngitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Skin infection		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Acute sinusitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Asymptomatic bacteriuria		

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Bacteraemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Bronchiolitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Cellulitis of male external genital organ		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Clostridium difficile colitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Clostridium difficile infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Cytomegalovirus viraemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Ear infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Enterocolitis infectious		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Epididymitis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Fungal infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gastric infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Hordeolum		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gastrointestinal infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Latent tuberculosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Molluscum contagiosum		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nail infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Nasal herpes		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Oesophageal candidiasis		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
Post procedural infection		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Proctitis herpes		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Pulpitis dental		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Scrotal infection		
subjects affected / exposed ^[20]	0 / 16 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0

Sialoadenitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tinea cruris			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tooth infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vaginal infection			
subjects affected / exposed ^[21]	1 / 8 (12.50%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Alpha haemolytic streptococcal infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Campylobacter infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Enterocolitis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Erysipelas			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis norovirus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gingivitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Helicobacter gastritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Helicobacter infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Herpes virus infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Infected cyst			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Kidney infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Localised infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Measles			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Moraxella infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Neutropenic sepsis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Onychomycosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ophthalmic herpes simplex			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Oral fungal infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Periorbital cellulitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pneumonia haemophilus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Pulmonary mycosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Septic shock			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Skin bacterial infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Splenic infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Staphylococcal sepsis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Streptococcal bacteraemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tinea pedis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Tinea versicolour			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection enterococcal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Viral pharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal mycotic infection			
subjects affected / exposed ^[22]	0 / 8 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Wound infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Humerus fracture			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			

Hypokalaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Decreased appetite		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Hypomagnesaemia		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Dehydration		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypophosphataemia		
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	2
Hyponatraemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypercalcaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hyperglycaemia		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Hyperuricaemia		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	2	0
Hypocalcaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypercholesterolaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hyperkalaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Tumour lysis syndrome		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Vitamin D deficiency		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Gout		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hyperlipidaemia		
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)
occurrences (all)	1	0
Hypertriglyceridaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypoalbuminaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypoglycaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Increased appetite		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Acidosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Diabetes mellitus		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Fluid overload		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Fluid retention		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Iron deficiency		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Magnesium deficiency		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Malnutrition		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Metabolic acidosis		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Type 2 diabetes mellitus		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Abnormal loss of weight		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Cachexia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Failure to thrive		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypermagnesaemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypernatraemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hyperphosphataemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
Hypochloraemia		
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

Hypoproteinaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Obesity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Zinc deficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	2 / 24 (8.33%)	1 / 12 (8.33%)	
occurrences (all)	3	1	
Neck pain			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	
occurrences (all)	1	0	

Notes:

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population

in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the male population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

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

Justification: Number of subjects exposed to this adverse event term is based on the female population in this study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 August 2016	<p>All subjects are now required to start prophylaxis treatment with pneumocystis jiroveci pneumonia (PCP) and antiviral therapy within 7 days prior to randomisation, whereas this was previously at investigator discretion. The phrasing of response assessment intervals has been revised for clarity from "on weeks 8,16, and 24, and then every 12 weeks thereafter," to "at the end of Cycles 2, 4, and 6, and then every 3 cycles thereafter". The shelf life of ublituximab has been increased to 36 months from 24 months when stored between +2 C / +8 C to reflect newly available stability data on ublituximab drug product. The tissue sample requirements at screening were revised for subjects with previous documentation of DLBCL subtype. For these subjects, tissue can now be submitted within +/-30 days of Day 1 of Cycle 1. If no documentation of DLBCL subtype is available prior to screening, a tissue sample must be submitted during the screening period to allow for central determination of DLBCL subtype prior to randomisation.</p> <p>Updated to include the most recent AE information related to ublituximab and TGR-1202 corresponding to the latest Investigator's Brochures.</p>
15 January 2017	<p>Women of childbearing potential were required to undergo monthly urine pregnancy testing beginning in Cycle 2.</p>
12 April 2017	<p>Additional cohorts were added, and eligibility criteria were expanded to allow enrolment of subjects with the following indolent types of NHL: FL, SLL, and MZL. Arm C was added to evaluate the combination of TGR-1202, ublituximab, and bendamustine in subjects with DLBCL and those with FL or SLL. Stratification by DLBCL subtype prior to randomisation was removed, however archived tissue for central determination of DLBCL subtype is still required within 30 days of Day 1 of Cycle 1. Number of subjects was expanded- up to approximately 400 subjects with DLBCL, up to approximately 400 subjects with FL or SLL, and up to approximately 60 subjects with MZL, provided no arms are closed for futility or at planned interim analyses. The number of potential study centres was expanded from up to 100 to up to 150, and the timeframe for enrolment was expanded from up to 14 months to up to 36 months. The window for use of medically acceptable methods of contraception for female subjects of child-bearing potential and male partners was expanded from throughout the study period and for 30 days after the last dose of either study drug to throughout the study period and for 4 months after the last dose of either study drug. Exclusion criteria 1, 3, 4,5, and 9 were updated. The response assessment schedule was revised from at the end of Cycles 2, 4, and 6 and then every 3 cycles thereafter, to during Cycles 3 and 6, and then every 3 cycles thereafter. The window for tumour evaluations was expanded from +/- 7 days to +/- 14 days. The screening period was expanded from 21 days to 28 days. Unilateral bone marrow aspirate and/or biopsy was only needed postbaseline to confirm a CR in subjects with marrow involvement at baseline and without FDG-avid disease. PET scans were previously required at baseline and routinely in subjects with FDG-avid disease. Study Assessment Table was amended and a second assessment table for subjects on the ublituximab+TGR-1202+bendamustine regimen added.</p>

01 October 2017	<p>Provided additional justification for the study of TGR-1202 monotherapy in subjects with MZL. Inclusion criterion 1(d), 2(a), 4(d) and exclusion criterion 9(c) were modified. The FL/SLL cohort was modified to include a Stage 1 to evaluate TGR-1202 monotherapy in up to 150 subjects prior to proceeding to Stage 2 which will randomise subjects to either TGR-1202 alone or in combination with ublituximab. The schedule for response evaluation previously stated to evaluate response "during" Cycles 3 and 6 and then every 3 cycles thereafter and was clarified to evaluate response "at the end of Cycle 3 and then within 14 days prior to Cycle 6, Day 1, and every 3 cycles thereafter (9, 12, etc.)". The study assessment tables were updated to specify that bone marrow aspirate and/or biopsy was optional only for subjects with DLBCL and required for subjects with FL, SLL, and MZL. Updated to include sparse sampling for population pharmacokinetics from all enrolled subjects, not just subjects in the DLBCL cohort, and the sparse sampling instructions were clarified. Updated to include information regarding a new vial size for ublituximab. Updated to clarify that pre-medications for bendamustine are recommended but optional and per institutional standard of care, which should at least include use of a corticosteroid, and that use of prophylactic growth factor support is allowed. Provided more specific instructions around dose-modifications in the event of diarrhoea and/or colitis. Reference to an interim analysis in the FL/SLL cohort was removed. Futility-stopping rules were added for the MZL cohort and the FL/SLL cohort based on Simon's 2-stage design.</p>
15 February 2018	<p>The number of trial sites was expanded from 150 to 200 sites. A cohort of subjects with MCL was added to the study, affecting the following sections: Primary objectives: amended to include efficacy objectives for MCL subjects; inclusion criteria 1, 2 and exclusion criteria 7, 8 were amended. Enrolment to Arm A of the DLBCL Cohort was suspended following accrual of a sufficient number of subjects. The schedule for response evaluation previously stated to evaluate response "at the end of Cycle 3 and then within 14 days prior to Cycle 6, Day 1, and every 3 cycles thereafter (9, 12, etc.)" and was amended to evaluate response, "at the end of Cycle 3 and then within 14 days prior to day 1 of Cycles 6, 9, and 12. After Cycle 12, response assessments should occur every 6 cycles or more frequently.". Amended to include background information and rationale for the addition of MCL subjects to this study. Modified to provide dose delay and/or modification guidelines for bendamustine for subjects experiencing occurrence of neutropenic fever or infection. The risk profile of ublituximab and TGR-1202 was updated to reflect the most recent safety data available from each agent. Other minor clarifications and administrative updates were made.</p>
20 August 2018	<p>The primary objectives of the study were re-written to reflect ORR as the primary endpoint for all cohorts. The key secondary objectives of CR rate for subjects with FL or SLL and PFS for subjects with DLBCL were revised to be Secondary Objectives. Inclusion Criterion 2 was amended. Stage 2 of the FL and SLL cohort was revised as follows: Stage 2 will only enrol subjects with FL, and no longer will enrol SLL, subjects will be randomised in a 3:1:1 ratio to receive ublituximab + TGR-1202 (Arm A), TGR-1202 monotherapy (Arm B), or ublituximab monotherapy (Arm D), subjects randomised to Arm D with documented progression will be eligible to cross-over to receive TGR-1202 monotherapy. Stage 2 of the MZL cohort was added to enrol an additional 60 subjects to receive the combination of ublituximab + TGR-1202. The duration of ublituximab therapy was truncated to stop at the end of Cycle 24 for any ublituximab-containing arm. Guidelines for holding anti-hypertensive medications during ublituximab infusions were updated. Eligibility for subjects with DLBCL was removed based on completion of target enrolment in the DLBCL cohorts. Statistical assumptions for the MZL, FL/SLL, and DLBCL cohorts were revised in accordance with recent Statistical Analysis Plans. Updated to provide further information on preferred PCP prophylactic agents. Updated to include the most recent AE information related to ublituximab and TGR-1202 corresponding to the latest Investigator's Brochures. Minor administrative updates and typographical errors were corrected throughout.</p>

20 September 2018	Inclusion Criterion 2C for subjects with MCL was clarified to state that the prior BTK inhibitor requirement is limited to only ibrutinib or acalabrutinib. Exclusion Criterion 1 was updated to allow palliative radiation therapy during the 21-day period prior to Day 1 of Cycle 1. Updated to include cytomegalovirus (CMV) surveillance for all subjects. Amended to provide additional guidance for ublituximab pre-medications. Revised to allow dose delays of any study medication for durations longer than 28 days to recover from toxicity. All dose modifications should now be reported in the Interactive Web Response System (IWRS), with questions regarding dose modifications referred to TG Therapeutics. Updated to provide clarification on the liver toxicity dose modification guidelines. Updated to include a cut-off date for the safety information for ublituximab and umbralisib. The latest safety information for each study drug is contained in the most recent investigator's brochures. Administrative updates and typographical errors were corrected throughout, including the changing of terminology from "patient" to "subject" and the inclusion of the generic name for "umbralisib" for TGR-1202.
19 November 2020	Cover page updated to add medical monitor and update study chair information. Eligibility criteria inclusion 1 updated to note that DLBCL is no longer enrolling, however subjects with SLL are eligible for enrolment. Eligibility criteria inclusion 2 updated to include FL, SLL, and MZL subjects that are treatment naïve or previously treated are now eligible. FL subjects are no longer required to be relapsed or refractory after ≥ 2 prior lines of systemic therapy, nor does the requirement to have received an anti-CD20 monoclonal antibody (mAb) and an alkylating agent apply. MZL subjects are no longer required to have prior treatment with one or more lines of prior treatment including at least one CD20-directed regimen (either as monotherapy or as chemoimmunotherapy) with documented failure to achieve at least PR or documented PD after the most recent systemic treatment regimen. Exclusion criteria 3 updated to clarify evidence of chronic active HBV is a detectable hepatitis b surface antigen. Updated to include a Stage 3 to include new dosing cohorts for subjects with FL, SLL or MZL. Ublituximab 36 milliliter per 900 mg vials are now available, protocol updated throughout to reflect the updated vials size, stability information, and dilution instructions. The storage of ublituximab if diluted in polyolefin (PO) infusion bags and lines can be extended to 48 hours refrigerated. Stage 3 enrolment and sample size added. Sparse Sampling PK added for subjects enrolled to Stage 3. Added to clarify umbralisib dosing cohorts in Stage 3. Updated to add details on crossover from Arm D to Arm B. Information on scheduling of ublituximab pre-medications for potential infusion related reactions (IRR) updated to be more clear, information on prophylaxis with antiviral agents for hepatitis B added for subjects with a prior history of hepatitis B and for those with a positive anti-HBc with negative HBsAg at screening. Updated contact information for any product quality complaint.

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.

Sponsor opted to terminate the study due to business decision.

Notes: