



Clinical trial results:

A Study to Evaluate the Safety and Efficacy of Nivolumab Monotherapy and Nivolumab in Combination With Ipilimumab in Pediatric Participants With High Grade Primary Central Nervous System (CNS) Malignancies (CheckMate 908)

Summary

EudraCT number	2016-004441-82
Trial protocol	ES GB DE SE NO NL PL Outside EU/EEA
Global end of trial date	17 January 2022

Results information

Result version number	v1 (current)
This version publication date	30 July 2022
First version publication date	30 July 2022

Trial information

Trial identification

Sponsor protocol code	CA209-908
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03130959
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001407-PIP02-15
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 March 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	17 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To estimate the safety and tolerability of study treatment in pediatric participants with primary high-grade CNS tumors.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 June 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 12
Country: Number of subjects enrolled	Brazil: 20
Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	France: 27
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Hong Kong: 2
Country: Number of subjects enrolled	Israel: 2
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Norway: 3
Country: Number of subjects enrolled	Poland: 1
Country: Number of subjects enrolled	Russian Federation: 5
Country: Number of subjects enrolled	Spain: 19
Country: Number of subjects enrolled	Sweden: 2
Country: Number of subjects enrolled	United Kingdom: 13
Country: Number of subjects enrolled	United States: 37
Worldwide total number of subjects	166
EEA total number of subjects	65

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)	3
Children (2-11 years)	87
Adolescents (12-17 years)	61
Adults (18-64 years)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

166 participants were treated

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Arm A1
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Arm description:

Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.

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

Dosage and administration details:

3 mg/kg was administered as an IV infusion every 2 weeks

Arm title	Arm B1
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Arm description:

Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.

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

Dosage and administration details:

3 mg/kg was administered as an IV infusion every 3 weeks for 4 doses, then 3 mg/kg as an IV infusion every 2 weeks thereafter

Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

1 mg/kg was administered as an IV infusion every 3 weeks for 4 doses

Arm title	Arm A2
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Arm description:
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.

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

Dosage and administration details:

3 mg/kg was administered as an IV infusion every 2 weeks

Arm title	Arm B2
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Arm description:

Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.

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

Dosage and administration details:

1 mg/kg was administered as an IV infusion every 3 weeks for 4 doses

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

3 mg/kg was administered as an IV infusion every 3 weeks for 4 doses, then 3 mg/kg as an IV infusion every 2 weeks thereafter

Arm title	Arm A3
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Arm description:

Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 3: participants with relapsed or resistant medulloblastoma.

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

Dosage and administration details:

3 mg/kg was administered as an IV infusion every 2 weeks

Arm title	Arm B3
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Arm description:

Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 3: participants with relapsed or resistant medulloblastoma.

Arm type	Experimental
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Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
1 mg/kg was administered as an IV infusion every 3 weeks for 4 doses	
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
3 mg/kg was administered as an IV infusion every 3 weeks for 4 doses, then 3 mg/kg as an IV infusion every 2 weeks thereafter	
Arm title	Arm A4
Arm description:	
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 4: participants with relapsed or resistant ependymoma.	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
3 mg/kg was administered as an IV infusion every 2 weeks	
Arm title	Arm B4
Arm description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 4: participants with relapsed or resistant ependymoma.	
Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
3 mg/kg was administered as an IV infusion every 3 weeks for 4 doses, then 3 mg/kg as an IV infusion every 2 weeks thereafter	
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
1 mg/kg was administered as an IV infusion every 3 weeks for 4 doses	
Arm title	Arm A5
Arm description:	
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).	
Arm type	Experimental

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
3 mg/kg was administered as an IV infusion every 2 weeks	
Arm title	Arm B5

Arm description:

Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).

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

Dosage and administration details:

1 mg/kg was administered as an IV infusion every 3 weeks for 4 doses

Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

3 mg/kg was administered as an IV infusion every 3 weeks for 4 doses, then 3 mg/kg as an IV infusion every 2 weeks thereafter

Number of subjects in period 1	Arm A1	Arm B1	Arm A2
Started	23	22	16
Completed	0	12	0
Not completed	23	10	16
Disease progression	19	7	12
Participant withdrew consent	-	1	-
Study drug toxicity	2	2	1
Not reported	-	-	-
Adverse Event unrelated to drug	-	-	1
Other reasons	-	-	-
Lost to follow-up	1	-	-
Subject request to discontinue therapy	-	-	1
Administrative reason by sponsor	1	-	1

Number of subjects in period 1	Arm B2	Arm A3	Arm B3
Started	15	15	15

Completed	1	0	9
Not completed	14	15	6
Disease progression	7	12	3
Participant withdrew consent	2	1	-
Study drug toxicity	2	1	1
Not reported	1	-	1
Adverse Event unrelated to drug	1	1	-
Other reasons	-	-	1
Lost to follow-up	-	-	-
Subject request to discontinue therapy	1	-	-
Administrative reason by sponsor	-	-	-

Number of subjects in period 1	Arm A4	Arm B4	Arm A5
Started	12	10	19
Completed	0	6	0
Not completed	12	4	19
Disease progression	6	3	15
Participant withdrew consent	-	-	-
Study drug toxicity	3	-	3
Not reported	-	-	-
Adverse Event unrelated to drug	1	-	1
Other reasons	1	-	-
Lost to follow-up	-	-	-
Subject request to discontinue therapy	1	1	-
Administrative reason by sponsor	-	-	-

Number of subjects in period 1	Arm B5
Started	19
Completed	4
Not completed	15
Disease progression	8
Participant withdrew consent	2
Study drug toxicity	3
Not reported	1
Adverse Event unrelated to drug	1
Other reasons	-
Lost to follow-up	-
Subject request to discontinue therapy	-
Administrative reason by sponsor	-

Baseline characteristics

Reporting groups

Reporting group title	Arm A1
Reporting group description:	
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.	
Reporting group title	Arm B1
Reporting group description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.	
Reporting group title	Arm A2
Reporting group description:	
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.	
Reporting group title	Arm B2
Reporting group description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.	
Reporting group title	Arm A3
Reporting group description:	
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 3: participants with relapsed or resistant medulloblastoma.	
Reporting group title	Arm B3
Reporting group description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 3: participants with relapsed or resistant medulloblastoma.	
Reporting group title	Arm A4
Reporting group description:	
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 4: participants with relapsed or resistant ependymoma.	
Reporting group title	Arm B4
Reporting group description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 4: participants with relapsed or resistant ependymoma.	
Reporting group title	Arm A5
Reporting group description:	
Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).	
Reporting group title	Arm B5
Reporting group description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).	

Reporting group values	Arm A1	Arm B1	Arm A2
Number of subjects	23	22	16
Age Categorical			
Units: Participants			
< 2 years old	0	0	0
>= 2 and < 12 years old	15	16	6

>= 12 and < 18 years old	6	5	6
>= 18 years old	2	1	4

Age continuous Units: years arithmetic mean standard deviation	9.1 ± 5.1	9.4 ± 4.3	12.1 ± 5.8
Sex: Female, Male Units: Participants			
Female	12	16	6
Male	11	6	10
Race/Ethnicity, Customized Units: Subjects			
White	19	11	13
Black or African American	2	4	0
Asian	0	2	1
American Indian or Alaska Native	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	2	4	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	3	2
Not Hispanic or Latino	7	10	4
Unknown or Not Reported	14	9	10

Reporting group values	Arm B2	Arm A3	Arm B3
Number of subjects	15	15	15
Age Categorical Units: Participants			
< 2 years old	0	0	0
>= 2 and < 12 years old	5	4	4
>= 12 and < 18 years old	8	11	9
>= 18 years old	2	0	2
Age continuous Units: years arithmetic mean standard deviation	12.6 ± 5.2	12.7 ± 3.5	12.7 ± 4.7
Sex: Female, Male Units: Participants			
Female	3	5	5
Male	12	10	10
Race/Ethnicity, Customized Units: Subjects			
White	14	14	14
Black or African American	0	0	1
Asian	1	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	0	1	0
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	2	0	1
Not Hispanic or Latino	5	6	4
Unknown or Not Reported	8	9	10

Reporting group values	Arm A4	Arm B4	Arm A5
Number of subjects	12	10	19
Age Categorical Units: Participants			
< 2 years old	0	1	1
>= 2 and < 12 years old	8	4	13
>= 12 and < 18 years old	3	3	4
>= 18 years old	1	2	1
Age continuous Units: years			
arithmetic mean	9.7	11.2	7.7
standard deviation	± 5.1	± 6.6	± 6.2
Sex: Female, Male Units: Participants			
Female	6	3	4
Male	6	7	15
Race/Ethnicity, Customized Units: Subjects			
White	7	9	18
Black or African American	1	0	1
Asian	3	1	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	1	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	1	2
Not Hispanic or Latino	5	5	8
Unknown or Not Reported	6	4	9

Reporting group values	Arm B5	Total	
Number of subjects	19	166	
Age Categorical Units: Participants			
< 2 years old	1	3	
>= 2 and < 12 years old	12	87	
>= 12 and < 18 years old	6	61	
>= 18 years old	0	15	
Age continuous Units: years			
arithmetic mean	8.3	-	
standard deviation	± 5.0	-	
Sex: Female, Male Units: Participants			
Female	10	70	

Male	9	96	
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Race/Ethnicity, Customized Units: Subjects			
White	13	132	
Black or African American	0	9	
Asian	2	10	
American Indian or Alaska Native	0	1	
Native Hawaiian or Other Pacific Islander	0	0	
Other	4	14	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	14	
Not Hispanic or Latino	6	60	
Unknown or Not Reported	13	92	

End points

End points reporting groups

Reporting group title	Arm A1
Reporting group description: Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.	
Reporting group title	Arm B1
Reporting group description: Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.	
Reporting group title	Arm A2
Reporting group description: Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.	
Reporting group title	Arm B2
Reporting group description: Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.	
Reporting group title	Arm A3
Reporting group description: Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 3: participants with relapsed or resistant medulloblastoma.	
Reporting group title	Arm B3
Reporting group description: Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 3: participants with relapsed or resistant medulloblastoma.	
Reporting group title	Arm A4
Reporting group description: Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 4: participants with relapsed or resistant ependymoma.	
Reporting group title	Arm B4
Reporting group description: Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 4: participants with relapsed or resistant ependymoma.	
Reporting group title	Arm A5
Reporting group description: Module A: nivolumab 3 mg/kg every 2 weeks. Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).	
Reporting group title	Arm B5
Reporting group description: Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter. Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).	
Subject analysis set title	Arm A1, Safety Lead-in
Subject analysis set type	Sub-group analysis
Subject analysis set description: Module A, Cohort 1	
Subject analysis set title	Arms A2-A5, Safety Lead-in
Subject analysis set type	Sub-group analysis
Subject analysis set description: Module A, Cohorts 2 through 5	
Subject analysis set title	Arms B2-B5, Safety Lead-in

Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Module B, Cohorts 2 through 5

Primary: Number of Safety Lead-In Participants with Dose Limiting Toxicities (DLTs)

End point title	Number of Safety Lead-In Participants with Dose Limiting Toxicities (DLTs) ^[1]
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End point description:

A dose-limiting toxicity (DLT) is defined as a drug-related AE occurring in the first 6 weeks of study treatment. A participant was considered evaluable for a DLT if study treatment was delayed > 2 weeks or was discontinued due to a related Adverse Event (AE), or if planned study treatment (3 doses of nivolumab in Module A, 2 doses of nivolumab plus ipilimumab in Module B) was administered and safety evaluation after 6 weeks on study is available to the study steering committee (SSC).

End point type	Primary
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End point timeframe:

up to 6 weeks post-dosing

Notes:

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

Justification: Only summary statistics planned for this endpoint.

End point values	Arm A1, Safety Lead-in	Arms A2-A5, Safety Lead-in	Arms B2-B5, Safety Lead-in	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	10	16	
Units: Number of participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Safety Lead-In Participants with Serious Adverse Events (SAEs)

End point title	Number of Safety Lead-In Participants with Serious Adverse Events (SAEs) ^[2]
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End point description:

The number of Safety Lead-In Participants who experienced a Serious Adverse Event (SAE) during the course of the study.

End point type	Primary
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End point timeframe:

up to 6 weeks post-dosing

Notes:

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

Justification: Only summary statistics planned for this endpoint.

End point values	Arm A1, Safety Lead-in	Arms A2-A5, Safety Lead-in	Arms B2-B5, Safety Lead-in	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	10	16	
Units: Number of participants	7	6	8	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Safety Lead-In Participants with Adverse Events (AEs) Leading to Discontinuation

End point title	Number of Safety Lead-In Participants with Adverse Events (AEs) Leading to Discontinuation ^[3]
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End point description:

The number of Safety Lead-In Participants who experienced an Adverse Event (AE) during the course of the study that lead to discontinuation of study therapy.

End point type	Primary
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End point timeframe:

up to 6 weeks post-dosing

Notes:

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

Justification: Only summary statistics planned for this endpoint.

End point values	Arm A1, Safety Lead-in	Arms A2-A5, Safety Lead-in	Arms B2-B5, Safety Lead-in	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	10	16	
Units: Number of participants	3	4	2	

Statistical analyses

No statistical analyses for this end point

Primary: Overall Survival (OS), Cohort 1 only

End point title	Overall Survival (OS), Cohort 1 only ^[4] ^[5]
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End point description:

Overall survival (OS) is defined as the time between the date of diagnosis and the date of death in Cohort 1.

End point type	Primary
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End point timeframe:

up to approximately 42 months

Notes:

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

Justification: Only summary statistics planned for this endpoint.

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A1	Arm B1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	22		
Units: months				
median (confidence interval 80%)	11.66 (10.32 to 16.46)	10.78 (9.13 to 15.77)		

Statistical analyses

No statistical analyses for this end point

Primary: Progression-Free Survival (PFS), Cohorts 2-4

End point title	Progression-Free Survival (PFS), Cohorts 2-4 ^{[6][7]}
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End point description:

Progression-free survival (PFS) is defined as the time from first dose to the date of the first documented tumor progression or death due to any cause.

End point type	Primary
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End point timeframe:

up to approximately 42 months

Notes:

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

Justification: Only summary statistics planned for this endpoint.

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A2	Arm B2	Arm A3	Arm B3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	15	15
Units: months				
median (confidence interval 80%)	1.74 (1.35 to 2.73)	1.31 (1.18 to 1.45)	1.38 (1.22 to 1.38)	2.76 (1.48 to 4.53)

End point values	Arm A4	Arm B4		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	10		
Units: months				
median (confidence interval 80%)	1.41 (1.41 to 2.60)	4.60 (1.41 to 5.39)		

Statistical analyses

No statistical analyses for this end point

Primary: Progression-Free Survival (PFS), Cohort 5 only

End point title	Progression-Free Survival (PFS), Cohort 5 only ^{[8][9]}
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End point description:

Progression-free survival (PFS) is defined as the time from first dose to the date of the first documented tumor progression or death due to any cause.

End point type	Primary
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End point timeframe:

up to approximately 42 months

Notes:

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

Justification: Only summary statistics planned for this endpoint.

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: months				
median (confidence interval 95%)	1.22 (1.08 to 1.31)	1.61 (1.31 to 3.45)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS), Cohort 1 only

End point title	Progression-Free Survival (PFS), Cohort 1 only ^[10]
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End point description:

Progression-free survival (PFS) is defined as the time from first dose to the date of the first documented tumor progression or death due to any cause.

Progression is defined as:

- $\geq 25\%$ increase in sum of the products of perpendicular diameters of enhancing lesions compared with the smallest tumor measurement
- Significant increase in T2 or fast fluid-attenuated inversion recovery (FLAIR) non-enhancing lesions on stable or increasing doses of corticosteroids
- Any new lesion
- Clear clinical deterioration not attributable to other causes apart from the tumor
- Failure to return for evaluation as a result of death or deteriorating condition
- Clear progression of non-measurable disease

End point type	Secondary
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End point timeframe:

From first dose to the date of the first documented tumor progression or death due to any cause (up to approximately 55 months)

Notes:

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A1	Arm B1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	22		
Units: Months				
median (confidence interval 95%)	6.21 (3.75 to 6.54)	4.53 (2.99 to 6.44)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival at 12 Months (OS12), Cohorts 1-4

End point title	Overall Survival at 12 Months (OS12), Cohorts 1-4 ^[11]
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End point description:

Overall survival at 12 months (OS12) is defined as the percentage of participants who are alive at 12 months, measured as the survival rate at 12 months from Kaplan-Meier product limit cumulative probability.

End point type	Secondary
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End point timeframe:

From first dose to up to 12 months after first dose

Notes:

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	16	15
Units: Percentage of participants				
number (confidence interval 95%)	47.3 (25.2 to 66.5)	42.9 (21.9 to 62.3)	37.5 (15.4 to 59.8)	32.8 (10.5 to 57.6)

End point values	Arm A3	Arm B3	Arm A4	Arm B4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	12	10
Units: Percentage of participants				
number (confidence interval 95%)	38.9 (14.3 to 63.2)	86.7 (56.4 to 96.5)	41.7 (15.2 to 66.5)	44.4 (13.6 to 71.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival at 6 Months (PFS6), Cohorts 2-5

End point title	Progression-Free Survival at 6 Months (PFS6), Cohorts 2-5 ^[12]
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End point description:

Progression-free survival at 6 months (PFS6) is defined as the percentage of participants who are progression free and alive at 6 months following first dose date, measured as the survival rate at 6 months from Kaplan-Meier product limit cumulative probability of progression free.

Progression is defined as:

- $\geq 25\%$ increase in sum of the products of perpendicular diameters of enhancing lesions compared with the smallest tumor measurement
- Significant increase in T2 or fast fluid-attenuated inversion recovery (FLAIR) non-enhancing lesions on stable or increasing doses of corticosteroids
- Any new lesion
- Clear clinical deterioration not attributable to other causes apart from the tumor
- Failure to return for evaluation as a result of death or deteriorating condition
- Clear progression of non-measurable disease

99999 = NA

End point type	Secondary
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End point timeframe:

From first dose to up to 6 months after first dose

Notes:

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A2	Arm B2	Arm A3	Arm B3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	15	15
Units: Percentage of participants				
number (confidence interval 95%)	9.4 (0.7 to 31.8)	14.3 (2.3 to 36.6)	0 (-99999 to 99999)	20.0 (4.9 to 42.4)

End point values	Arm A4	Arm B4	Arm A5	Arm B5
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	19	19
Units: Percentage of participants				
number (confidence interval 95%)	20.0 (3.1 to 47.5)	11.4 (0.6 to 39.5)	5.3 (0.4 to 21.4)	14.0 (2.8 to 34.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS), Cohorts 2-5

End point title	Overall Survival (OS), Cohorts 2-5 ^[13]
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End point description:

Overall survival (OS) is defined as the time between date of first dose and the date of death for Cohorts 2-5.

99999 = NA

End point type	Secondary
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End point timeframe:

From first dose to the date of death (up to approximately 55 months)

Notes:

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A2	Arm B2	Arm A3	Arm B3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	15	15
Units: Months				
median (confidence interval 95%)	6.67 (2.99 to 14.62)	6.47 (2.14 to 13.17)	7.36 (2.46 to 30.23)	22.21 (13.77 to 9999)

End point values	Arm A4	Arm B4	Arm A5	Arm B5
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	10	19	19
Units: Months				
median (confidence interval 95%)	5.70 (1.81 to 99999)	9.82 (2.50 to 99999)	5.91 (1.97 to 7.98)	8.48 (3.45 to 17.28)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treated Participants with Adverse Events (AEs)

End point title	Number of Treated Participants with Adverse Events (AEs)
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End point description:

The number of treated participants who experienced an Adverse Event (AE) during the course of the study.

An AE is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug.

End point type	Secondary
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End point timeframe:

From first dose to 30 days post-last dose (up to approximately an average of 3 months and a maximum of 51 months)

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	16	15
Units: Participants	23	21	15	14

End point values	Arm A3	Arm B3	Arm A4	Arm B4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	12	10
Units: Participants	14	15	12	10

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: Participants	18	18		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treated Participants with Serious Adverse Events (SAEs)

End point title	Number of Treated Participants with Serious Adverse Events (SAEs)
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End point description:

The number of treated participants who experienced a Serious Adverse Event (SAE) during the course of the study.

SAE is defined as any untoward medical occurrence that, at any dose:

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or causes prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Is an important medical event

Note: The reporting timeframe of the SAEs for this Outcome Measure (first dose to 30 days post last dose) differs than that of the reporting timeframe of the SAEs reported under the AE section of the results form (first dose to 100 days post last dose) and thus, the data in each table of SAEs reflects the specific timeframe applied.

End point type	Secondary
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End point timeframe:

From first dose to 30 days post-last dose (up to approximately an average of 3 months and a maximum of 51 months)

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	16	15
Units: Participants	10	14	10	9

End point values	Arm A3	Arm B3	Arm A4	Arm B4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	12	10
Units: Participants	6	7	7	5

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: Participants	13	14		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treated Participants with Drug-Related Adverse Events

End point title	Number of Treated Participants with Drug-Related Adverse Events
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End point description:

The number of treated participants who experienced a Drug-Related Adverse Event during the course of the study.

An AE is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug.

End point type	Secondary
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End point timeframe:

From first dose to 30 days post-last dose (up to approximately an average of 3 months and a maximum of 51 months)

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	16	15
Units: Participants	14	16	12	8

End point values	Arm A3	Arm B3	Arm A4	Arm B4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	12	10
Units: Participants	6	11	6	6

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: Participants	11	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treated Participants with Adverse Events Leading to Discontinuation

End point title	Number of Treated Participants with Adverse Events Leading to Discontinuation
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End point description:

The number of treated participants who experienced an Adverse Event leading to discontinuation during the course of the study.

An AE is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporally associated with the use of study drug, whether or not considered related to the study drug.

End point type	Secondary
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End point timeframe:

From first dose to 30 days post-last dose (up to approximately an average of 3 months and a maximum of 51 months)

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	16	15
Units: Participants	4	7	3	5

End point values	Arm A3	Arm B3	Arm A4	Arm B4
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	12	10
Units: Participants	2	3	6	1

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: Participants	6	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treated Participant Deaths

End point title	Number of Treated Participant Deaths
End point description:	The number of treated participants who died during the course of the study.
End point type	Secondary
End point timeframe:	From first dose to the date of death (up to approximately 55 months)

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	22	16	15
Units: Participants	18	18	12	13

End point values	Arm A3	Arm B3	Arm A4	Arm B4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	12	10
Units: Participants	12	11	9	7

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: Participants	18	15		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treated Participant with Laboratory Abnormalities - Liver

End point title	Number of Treated Participant with Laboratory Abnormalities - Liver
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End point description:

The number of treated participants who experienced a laboratory abnormality of the liver during the course of the study.

Aspartate aminotransferase (AST)

Alanine aminotransferase (ALT)

Upper Limit of Normal (ULN)

Units per Liter (U/L)

Results reported in International System of Units (SI)

End point type	Secondary
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End point timeframe:

From first dose to 30 days post-last dose (up to approximately an average of 3 months and a maximum of 51 months)

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	21	16	12
Units: Participants				
ALT OR AST > 3XULN	3	7	2	0
ALT OR AST > 5XULN	2	4	1	0
ALT OR AST > 10XULN	2	1	1	0
ALT OR AST > 20XULN	0	1	1	0
TOTAL BILIRUBIN > 2XULN	0	2	0	0
ALP > 1.5XULN	0	0	0	0
ALT or AST>3xULN w/ Tbili>1.5*ULN within 1 day	0	1	1	0
ALT or AST>3xULN w/ Tbili>1.5*ULN within 30 days	0	2	1	0
ALT or AST>3xULN w/ Tbili>2*ULN within 1 day	0	1	0	0
ALT or AST>3xULN w/ Tbili>2*ULN within 30 days	0	2	0	0

End point values	Arm A3	Arm B3	Arm A4	Arm B4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	14	11	10

Units: Participants				
ALT OR AST > 3XULN	0	3	1	1
ALT OR AST > 5XULN	0	1	0	1
ALT OR AST > 10XULN	0	1	0	1
ALT OR AST > 20XULN	0	0	0	0
TOTAL BILIRUBIN > 2XULN	0	0	0	0
ALP > 1.5XULN	0	0	0	0
ALT or AST>3xULN w/ Tbili>1.5*ULN within 1 day	0	0	0	0
ALT or AST>3xULN w/ Tbili>1.5*ULN within 30 days	0	0	0	0
ALT or AST>3xULN w/ Tbili>2*ULN within 1 day	0	0	0	0
ALT or AST>3xULN w/ Tbili>2*ULN within 30 days	0	0	0	0

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: Participants				
ALT OR AST > 3XULN	3	2		
ALT OR AST > 5XULN	2	2		
ALT OR AST > 10XULN	2	2		
ALT OR AST > 20XULN	0	2		
TOTAL BILIRUBIN > 2XULN	1	1		
ALP > 1.5XULN	0	1		
ALT or AST>3xULN w/ Tbili>1.5*ULN within 1 day	0	1		
ALT or AST>3xULN w/ Tbili>1.5*ULN within 30 days	0	1		
ALT or AST>3xULN w/ Tbili>2*ULN within 1 day	0	1		
ALT or AST>3xULN w/ Tbili>2*ULN within 30 days	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treated Participant with Laboratory Abnormalities - Thyroid

End point title	Number of Treated Participant with Laboratory Abnormalities - Thyroid
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End point description:

The number of treated participants who experienced a laboratory abnormality of the thyroid during the course of the study.

Free T3 (FT3)
Free T4 (FT4)
Thyroid stimulating hormone (TSH)
Lower Limit of Normal (LLN)
Upper limit of normal (ULN)

End point type	Secondary
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End point timeframe:

From first dose to 30 days post-last dose (up to approximately an average of 3 months and a maximum of 51 months)

End point values	Arm A1	Arm B1	Arm A2	Arm B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	10	8
Units: Participants				
TSH > ULN	2	1	3	1
TSH > ULN, WITH TSH ≤ ULN AT BASELINE	2	1	2	1
TSH > ULN, WITH AT LEAST ONE FT3/FT4 TEST < LLN	1	1	1	1
TSH > ULN, WITH ALL OTHER FT3/FT4 TEST ≥ LLN	0	0	1	0
TSH > ULN, WITH FT3/FT4 TEST MISSING	1	0	1	0
TSH < LLN	3	7	2	2
TSH < LLN, WITH TSH ≥ LLN AT BASELINE	3	6	1	2
TSH < LLN, LLN WITH AT LEAST ONE FT3/FT4 TEST > ULN	0	1	0	0
TSH < LLN, WITH ALL OTHER FT3/FT4 TEST ≤ ULN	1	2	1	2
TSH < LLN, WITH FT3/FT4 TEST MISSING	2	4	1	0

End point values	Arm A3	Arm B3	Arm A4	Arm B4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	13	9	8
Units: Participants				
TSH > ULN	3	7	2	3
TSH > ULN, WITH TSH ≤ ULN AT BASELINE	0	7	1	3
TSH > ULN, WITH AT LEAST ONE FT3/FT4 TEST < LLN	1	6	2	2
TSH > ULN, WITH ALL OTHER FT3/FT4 TEST ≥ LLN	0	0	0	0
TSH > ULN, WITH FT3/FT4 TEST MISSING	2	1	0	1
TSH < LLN	0	3	0	0
TSH < LLN, WITH TSH ≥ LLN AT BASELINE	0	1	0	0
TSH < LLN, LLN WITH AT LEAST ONE FT3/FT4 TEST > ULN	0	2	0	0
TSH < LLN, WITH ALL OTHER FT3/FT4 TEST ≤ ULN	0	1	0	0

TSH < LLN, WITH FT3/FT4 TEST MISSING	0	0	0	0
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End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	14		
Units: Participants				
TSH > ULN	1	5		
TSH > ULN, WITH TSH <= ULN AT BASELINE	1	2		
TSH > ULN, WITH AT LEAST ONE FT3/FT4 TEST < LLN	0	2		
TSH > ULN, WITH ALL OTHER FT3/FT4 TEST >= LLN	1	3		
TSH > ULN, WITH FT3/FT4 TEST MISSING	0	0		
TSH < LLN	0	1		
TSH < LLN, WITH TSH >= LLN AT BASELINE	0	1		
TSH<LLN, LLN WITH AT LEAST ONE FT3/FT4 TEST>ULN	0	0		
TSH < LLN, WITH ALL OTHER FT3/FT4 TEST <= ULN	0	1		
TSH < LLN, WITH FT3/FT4 TEST MISSING	0	0		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Overall Survival (OS), Cohort 1 only - Extended Collection

End point title	Overall Survival (OS), Cohort 1 only - Extended Collection ^[14]
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End point description:

Overall survival (OS) is defined as the time between the date of diagnosis and the date of death in Cohort 1. Note: This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 17-Jan-2022).

End point type	Post-hoc
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End point timeframe:

From first dose to the date of death (up to approximately 55 months)

Notes:

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A1	Arm B1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	22		
Units: Months				
median (confidence interval 80%)	11.66 (10.32 to 23.49)	10.78 (9.13 to 15.77)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Progression-Free Survival (PFS), Cohorts 2-4 - Extended Collection

End point title	Progression-Free Survival (PFS), Cohorts 2-4 - Extended Collection ^[15]
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End point description:

Progression-free survival (PFS) is defined as the time from first dose to the date of the first documented tumor progression or death due to any cause. Note: This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 17-Jan-2022).

Progression is defined as:

- $\geq 25\%$ increase in sum of the products of perpendicular diameters of enhancing lesions compared with the smallest tumor measurement
- Significant increase in T2 or fast fluid-attenuated inversion recovery (FLAIR) non-enhancing lesions on stable or increasing doses of corticosteroids
- Any new lesion
- Clear clinical deterioration not attributable to other causes apart from the tumor
- Failure to return for evaluation as a result of death or deteriorating condition
- Clear progression of non-measurable disease

End point type	Post-hoc
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End point timeframe:

From first dose to the date of the first documented tumor progression or death due to any cause (up to approximately 55 months)

Notes:

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A2	Arm B2	Arm A3	Arm B3
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	15	15
Units: Months				
median (confidence interval 80%)	1.74 (1.35 to 2.73)	1.38 (1.22 to 1.48)	1.38 (1.22 to 1.38)	2.69 (1.48 to 4.53)

End point values	Arm A4	Arm B4		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	12	10		
Units: Months				
median (confidence interval 80%)	1.41 (1.38 to	4.60 (1.41 to		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Progression-Free Survival (PFS), Cohort 5 only - Extended Collection

End point title	Progression-Free Survival (PFS), Cohort 5 only - Extended Collection ^[16]
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End point description:

Progression-free survival (PFS) is defined as the time from first dose to the date of the first documented tumor progression or death due to any cause. Note: This outcome measure represents an updated version of the primary endpoint to include additional data collection that has occurred after the primary completion date. (Assessments were made until 17-Jan-2022).

Progression is defined as:

- $\geq 25\%$ increase in sum of the products of perpendicular diameters of enhancing lesions compared with the smallest tumor measurement
- Significant increase in T2 or fast fluid-attenuated inversion recovery (FLAIR) non-enhancing lesions on stable or increasing doses of corticosteroids
- Any new lesion
- Clear clinical deterioration not attributable to other causes apart from the tumor
- Failure to return for evaluation as a result of death or deteriorating condition
- Clear progression of non-measurable disease

End point type	Post-hoc
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End point timeframe:

From first dose to the date of the first documented tumor progression or death due to any cause (up to approximately 55 months)

Notes:

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

Justification: Endpoints are cohort and/or safety lead-in specific and do not report for all arms.

End point values	Arm A5	Arm B5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	19		
Units: Months				
median (confidence interval 95%)	1.22 (1.08 to 1.31)	1.61 (1.31 to 3.45)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality was assessed from first dose to study completion (up to approximately 55 months). SAEs and Other AEs were monitored from first dose to 100 days after last dose (up to an average of 5 months and to a maximum of 53 months).

Adverse event reporting additional description:

Note: The reporting timeframe of the below SAEs (first dose to 100 days post last dose) differs than that of the reporting timeframe of the SAEs reported under the Outcome Measures section of the results form (first dose to 30 days post last dose) and thus, the data in each table of SAEs reflects the specific timeframe applied.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Arm A1
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Reporting group description:

Module A: nivolumab 3 mg/kg every 2 weeks.

Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.

Reporting group title	Arm B1
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Reporting group description:

Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter.

Cohort 1: participants with newly-diagnosed DIPG, including midline glioma with H3K27M mutation.

Reporting group title	Arm A2
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Reporting group description:

Module A: nivolumab 3 mg/kg every 2 weeks.

Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.

Reporting group title	Arm B2
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Reporting group description:

Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter.

Cohort 2: participants with recurrent or progressive non-brainstem HGG, regardless of mutation status, including glioblastoma.

Reporting group title	Arm A3
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Reporting group description:

Module A: nivolumab 3 mg/kg every 2 weeks.

Cohort 3: participants with relapsed or resistant medulloblastoma.

Reporting group title	Arm B3
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Reporting group description:

Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter.

Cohort 3: participants with relapsed or resistant medulloblastoma.

Reporting group title	Arm A4
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Reporting group description:

Module A: nivolumab 3 mg/kg every 2 weeks.

Cohort 4: participants with relapsed or resistant ependymoma.

Reporting group title	Arm B4
Reporting group description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter.	
Cohort 4: participants with relapsed or resistant ependymoma.	
Reporting group title	Arm A5
Reporting group description:	
Module A: nivolumab 3 mg/kg every 2 weeks.	
Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).	
Reporting group title	Arm B5
Reporting group description:	
Module B: nivolumab 3 mg/kg + ipilimumab 1 mg/kg every 3 weeks, for 4 doses, then nivolumab 3 mg/kg every 2 weeks thereafter.	
Cohort 5: participants with other recurrent subtypes of high-grade CNS malignancy (eg, pineoblastoma, AT/RT, germ cell tumor, and others).	

Serious adverse events	Arm A1	Arm B1	Arm A2
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 23 (73.91%)	16 / 22 (72.73%)	13 / 16 (81.25%)
number of deaths (all causes)	18	18	12
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	9 / 23 (39.13%)	7 / 22 (31.82%)	6 / 16 (37.50%)
occurrences causally related to treatment / all	0 / 9	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 8	0 / 6	0 / 6
Neoplasm			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	1 / 23 (4.35%)	3 / 22 (13.64%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	1 / 1	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated adverse reaction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multisystem inflammatory syndrome in children			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (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
Bronchospasm			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 16 (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
Hypoxia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (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
Chest X-ray abnormal			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (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

Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain herniation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Facial bones fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt malfunction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (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
Dyskinesia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial nerve disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 23 (4.35%)	2 / 22 (9.09%)	0 / 16 (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
Hemiparesis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 23 (0.00%)	4 / 22 (18.18%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Intracranial pressure increased			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Lethargy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor dysfunction			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Myoclonus			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological decompensation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (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
Status epilepticus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ascites			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (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
Constipation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	2 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 23 (0.00%)	3 / 22 (13.64%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Hepatitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Hepatitis acute			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Toxic skin eruption			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Bladder dysfunction			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Urinary incontinence			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Mobility decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Spinal deformity			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Infections and infestations			
Bacterial infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Coronavirus infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea infectious			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Gastroenteritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Vascular device infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection staphylococcal			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (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
Steroid diabetes			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm B2	Arm A3	Arm B3
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 15 (80.00%)	7 / 15 (46.67%)	10 / 15 (66.67%)
number of deaths (all causes)	13	12	11
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	5 / 15 (33.33%)	6 / 15 (40.00%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 3	0 / 6	0 / 0
Neoplasm			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neoplasm progression			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Schwannoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
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			
Hypertension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated adverse reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multisystem inflammatory syndrome in children			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Pneumonitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chest X-ray abnormal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain herniation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt malfunction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Wound dehiscence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyskinesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial nerve disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	2 / 15 (13.33%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	1 / 3	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	0 / 15 (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
Lethargy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor dysfunction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological decompensation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (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
Ascites			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Enterocolitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Bladder dysfunction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Mobility decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal deformity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Device related infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Staphylococcal bacteraemia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (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
Tonsillitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection staphylococcal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (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
Hypocalcaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (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
Hypokalaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Steroid diabetes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm A4	Arm B4	Arm A5
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 12 (91.67%)	6 / 10 (60.00%)	14 / 19 (73.68%)
number of deaths (all causes)	9	7	18
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	7 / 12 (58.33%)	5 / 10 (50.00%)	7 / 19 (36.84%)
occurrences causally related to treatment / all	0 / 8	0 / 5	0 / 9
deaths causally related to treatment / all	0 / 6	0 / 5	0 / 7

Neoplasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 19 (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
Schwannoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour flare			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
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			
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General physical health deterioration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 12 (8.33%)	2 / 10 (20.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	1 / 1	0 / 3	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (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
Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated adverse reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multisystem inflammatory syndrome in children			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (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
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest X-ray abnormal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Brain herniation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Shunt malfunction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (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
Wound dehiscence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyskinesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial nerve disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (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
Haemorrhage intracranial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 12 (8.33%)	2 / 10 (20.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	3 / 12 (25.00%)	2 / 10 (20.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Motor dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (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
Neurological decompensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic skin eruption			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Bladder dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Mobility decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal deformity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacterial infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection staphylococcal			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Steroid diabetes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Arm B5		
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Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 19 (78.95%)		
number of deaths (all causes)	15		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	7 / 19 (36.84%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 6		
Neoplasm			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasm progression			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schwannoma			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour flare			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Hypotension			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General physical health deterioration			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences causally related to treatment / all	1 / 5		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersensitivity			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune-mediated adverse reaction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multisystem inflammatory syndrome in children			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Aspiration			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Psychotic disorder			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest X-ray abnormal			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic enzyme increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Brain herniation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infusion related reaction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shunt malfunction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysarthria			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyskinesia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Facial nerve disorder			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage intracranial			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intracranial pressure increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lethargy			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Motor dysfunction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myoclonus			

subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorder				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neurological decompensation				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Partial seizures				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peripheral motor neuropathy				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Somnolence				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Status epilepticus				

subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Diarrhoea				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated enterocolitis				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				

Autoimmune hepatitis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis acute			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Toxic skin eruption			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Bladder dysfunction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Mobility decreased			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal deformity			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bacterial infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronavirus infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea infectious			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			

subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Measles				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	1 / 19 (5.26%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Staphylococcal infection				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
subjects affected / exposed	0 / 19 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				

subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular device infection			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection staphylococcal			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypocalcaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypophagia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Steroid diabetes			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Arm A1	Arm B1	Arm A2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 23 (95.65%)	21 / 22 (95.45%)	15 / 16 (93.75%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Melanocytic naevus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Embolism			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Extremity necrosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application site pruritus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	3 / 23 (13.04%)	0 / 22 (0.00%)	2 / 16 (12.50%)
occurrences (all)	3	0	2
Chills			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Device related thrombosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	8 / 23 (34.78%)	6 / 22 (27.27%)	4 / 16 (25.00%)
occurrences (all)	10	6	5
Gait disturbance			

subjects affected / exposed	4 / 23 (17.39%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	4	1	0
General physical health deterioration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Oedema peripheral			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	5 / 23 (21.74%)	6 / 22 (27.27%)	2 / 16 (12.50%)
occurrences (all)	7	14	3
Sensation of foreign body			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 2	1 / 22 (4.55%) 1	0 / 16 (0.00%) 0
Infusion related hypersensitivity reaction subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 22 (4.55%) 1	0 / 16 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	2 / 22 (9.09%) 2	0 / 16 (0.00%) 0
Reproductive system and breast disorders			
Testicular pain subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 22 (4.55%) 1	0 / 16 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 5	4 / 22 (18.18%) 8	3 / 16 (18.75%) 3
Dysphonia subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	1 / 22 (4.55%) 1	0 / 16 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	1 / 22 (4.55%) 1	0 / 16 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 4	2 / 22 (9.09%) 5	0 / 16 (0.00%) 0

Hypoxia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Nasal dryness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 23 (8.70%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	3	1	1
Sleep apnoea syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	2 / 16 (12.50%)
occurrences (all)	1	0	2
Behaviour disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Dysphemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	4 / 23 (17.39%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	4	2	0
Irritability			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Mood swings			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Phonophobia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Investigations			

Alanine aminotransferase increased subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 4	6 / 22 (27.27%) 7	2 / 16 (12.50%) 2
Amylase increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Anion gap increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	1 / 16 (6.25%) 2
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 5	4 / 22 (18.18%) 5	2 / 16 (12.50%) 2
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Blood bicarbonate increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Blood chloride decreased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Blood creatine increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Blood creatinine decreased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	1 / 16 (6.25%) 1
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 2	1 / 22 (4.55%) 1	0 / 16 (0.00%) 0
Blood lactate dehydrogenase decreased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	1 / 16 (6.25%) 1
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Blood magnesium decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood sodium increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Blood uric acid increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	0	1	2
Haematocrit decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Intestinal transit time increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	5	0	0
Mean cell volume decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mean cell volume increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	2	0	3
Neutrophil count increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Red blood cell count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Red blood cell count increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin turgor decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thyroxine free decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thyroxine free increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			

subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Tri-iodothyronine free increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	1 / 16 (6.25%) 1
Weight decreased subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 3	7 / 22 (31.82%) 8	1 / 16 (6.25%) 1
Weight increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	2 / 22 (9.09%) 2	0 / 16 (0.00%) 0
White blood cell count decreased subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 3	1 / 22 (4.55%) 2	1 / 16 (6.25%) 1
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 22 (4.55%) 1	0 / 16 (0.00%) 0
Contusion subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Facial bones fracture subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 22 (0.00%) 0	0 / 16 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 3	0 / 22 (0.00%) 0	1 / 16 (6.25%) 1
Fracture			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Shunt malfunction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Stoma site discharge			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Vascular access complication			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Vascular access site discharge			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vascular access site pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vascular access site rash			

subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Wound			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Von Willebrand's disease			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Allodynia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Altered state of consciousness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Aphasia			
subjects affected / exposed	3 / 23 (13.04%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	3	1	0
Areflexia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ataxia			

subjects affected / exposed	2 / 23 (8.70%)	6 / 22 (27.27%)	1 / 16 (6.25%)
occurrences (all)	2	6	1
Balance disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Consciousness fluctuating			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Diplegia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Dizziness			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Dysarthria			
subjects affected / exposed	0 / 23 (0.00%)	3 / 22 (13.64%)	0 / 16 (0.00%)
occurrences (all)	0	4	0
Epilepsy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Facial paralysis			
subjects affected / exposed	1 / 23 (4.35%)	3 / 22 (13.64%)	1 / 16 (6.25%)
occurrences (all)	1	3	1
Facial paresis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Haemorrhage intracranial			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	9 / 23 (39.13%)	10 / 22 (45.45%)	7 / 16 (43.75%)
occurrences (all)	17	19	10
Hemianopia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	4 / 23 (17.39%)	7 / 22 (31.82%)	0 / 16 (0.00%)
occurrences (all)	5	7	0
Hydrocephalus			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Hypersomnia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
IIIrd nerve disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Intracranial pressure increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Meningism			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Motor dysfunction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			

subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nervous system disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	2 / 23 (8.70%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	3	1	0
Paraparesis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Paresis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Seizure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Somnolence			

subjects affected / exposed	3 / 23 (13.04%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	3	1	0
Speech disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Taste disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Trigeminal nerve disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
VIIth nerve disorder			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	2 / 16 (12.50%)
occurrences (all)	2	1	3
Coagulopathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Lymphadenopathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0

Neutropenia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	2
Pancytopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Ear pain			
subjects affected / exposed	2 / 23 (8.70%)	3 / 22 (13.64%)	0 / 16 (0.00%)
occurrences (all)	2	4	0
Ear pruritus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Tympanic membrane perforation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Eye disorders			

Blepharospasm			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Blindness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Corneal epithelium defect			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	2 / 23 (8.70%)	3 / 22 (13.64%)	1 / 16 (6.25%)
occurrences (all)	3	4	1
Dry eye			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Eye movement disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	1	1	1

Eye swelling			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Mydriasis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pupillary reflex impaired			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	2 / 16 (12.50%)
occurrences (all)	0	2	2
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	4 / 23 (17.39%)	7 / 22 (31.82%)	2 / 16 (12.50%)
occurrences (all)	25	9	6
Abdominal pain upper			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Anal haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Anal incontinence			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	2
Colitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	5 / 23 (21.74%)	5 / 22 (22.73%)	5 / 16 (31.25%)
occurrences (all)	8	7	5
Diarrhoea			
subjects affected / exposed	6 / 23 (26.09%)	3 / 22 (13.64%)	4 / 16 (25.00%)
occurrences (all)	9	4	8
Dry mouth			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Duodenitis			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	3 / 23 (13.04%)	4 / 22 (18.18%)	1 / 16 (6.25%)
occurrences (all)	4	4	1
Flatulence			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 23 (4.35%)	3 / 22 (13.64%)	2 / 16 (12.50%)
occurrences (all)	1	3	2
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Lip swelling			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	8 / 23 (34.78%)	4 / 22 (18.18%)	4 / 16 (25.00%)
occurrences (all)	12	5	4
Oral dysaesthesia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Paraesthesia oral			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Post-tussive vomiting			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tongue oedema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	8 / 23 (34.78%)	11 / 22 (50.00%)	7 / 16 (43.75%)
occurrences (all)	11	19	9
Hepatobiliary disorders			
Hepatitis acute			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Alopecia			
subjects affected / exposed	1 / 23 (4.35%)	2 / 22 (9.09%)	1 / 16 (6.25%)
occurrences (all)	1	2	1
Angioedema			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Blister			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Circumoral oedema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 23 (0.00%)	3 / 22 (13.64%)	0 / 16 (0.00%)
occurrences (all)	0	5	0
Eczema			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Erythema			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Keratosis pilaris			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	3 / 23 (13.04%)	2 / 22 (9.09%)	1 / 16 (6.25%)
occurrences (all)	4	3	1
Rash			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	2 / 16 (12.50%)
occurrences (all)	1	1	3
Rash erythematous			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	3 / 23 (13.04%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	3 / 16 (18.75%)
occurrences (all)	1	1	3
Rash papular			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin disorder			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Skin exfoliation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	3	0	0
Skin irritation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Haematuria			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Neurogenic bladder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Nocturia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Oliguria			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Diabetes insipidus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 23 (0.00%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Hypothyroidism			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 23 (8.70%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	2	2	0
Arthritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	1 / 23 (4.35%)	2 / 22 (9.09%)	1 / 16 (6.25%)
occurrences (all)	1	2	1
Dactylitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Mastication disorder			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Muscular weakness			
subjects affected / exposed	2 / 23 (8.70%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	2	2	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	3 / 23 (13.04%)	3 / 22 (13.64%)	0 / 16 (0.00%)
occurrences (all)	3	3	0
Spinal pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Torticollis			

subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	0	2	1
Enterobiasis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Febrile infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis Escherichia coli			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infection parasitic			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Lip infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Localised infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	1	1	1
Oral candidiasis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Paronychia			
subjects affected / exposed	2 / 23 (8.70%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	2	0	0
Pneumococcal infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	2 / 23 (8.70%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Sepsis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	2 / 16 (12.50%)
occurrences (all)	0	2	3
Sinusitis bacterial			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	5 / 23 (21.74%)	3 / 22 (13.64%)	2 / 16 (12.50%)
occurrences (all)	14	11	3
Urinary tract infection			
subjects affected / exposed	1 / 23 (4.35%)	3 / 22 (13.64%)	2 / 16 (12.50%)
occurrences (all)	3	4	2

Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 23 (13.04%)	4 / 22 (18.18%)	3 / 16 (18.75%)
occurrences (all)	7	4	3
Dehydration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	2	0
Hyperkalaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypernatraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hypoalbuminaemia			

subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypochloraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Hypokalaemia			
subjects affected / exposed	1 / 23 (4.35%)	2 / 22 (9.09%)	0 / 16 (0.00%)
occurrences (all)	1	2	0
Hypomagnesaemia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 22 (0.00%)	1 / 16 (6.25%)
occurrences (all)	1	0	1
Polydipsia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 22 (4.55%)	0 / 16 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Arm B2	Arm A3	Arm B3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 15 (93.33%)	14 / 15 (93.33%)	14 / 15 (93.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Myelodysplastic syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Deep vein thrombosis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Embolism			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Extremity necrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	3 / 15 (20.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Hypotension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Application site pruritus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	3 / 15 (20.00%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	3	0	4
Chills			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Facial pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	3 / 15 (20.00%)	2 / 15 (13.33%)	4 / 15 (26.67%)
occurrences (all)	3	2	6
Gait disturbance			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
General physical health deterioration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Generalised oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	1	2
Pain			

subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	4 / 15 (26.67%) 6	1 / 15 (6.67%) 3	2 / 15 (13.33%) 3
Sensation of foreign body subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Xerosis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Immune system disorders Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Infusion related hypersensitivity reaction subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Reproductive system and breast disorders Testicular pain subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Bronchospasm subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0

Cough			
subjects affected / exposed	3 / 15 (20.00%)	2 / 15 (13.33%)	3 / 15 (20.00%)
occurrences (all)	3	2	6
Dysphonia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Epistaxis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	0	0	3
Hypoxia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Increased upper airway secretion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	1	0	4
Nasal dryness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	2	2
Productive cough			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	3
Sleep apnoea syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1

Sneezing			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 15 (6.67%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	1	2	0
Behaviour disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dysphemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Irritability			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Mood swings			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Phonophobia			

subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Restlessness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Suicidal ideation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 15 (20.00%)	2 / 15 (13.33%)	4 / 15 (26.67%)
occurrences (all)	5	2	5
Amylase increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Anion gap increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 15 (13.33%)	1 / 15 (6.67%)	5 / 15 (33.33%)
occurrences (all)	2	1	7
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blood bicarbonate increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blood chloride decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blood creatine increased			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Blood creatinine decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	0	0	3
Blood urea increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	1	2
Blood uric acid increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Haematocrit decreased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Intestinal transit time increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Liver function test increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 15 (6.67%)	2 / 15 (13.33%)	3 / 15 (20.00%)
occurrences (all)	1	3	6
Mean cell volume decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Mean cell volume increased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Neutrophil count decreased			
subjects affected / exposed	1 / 15 (6.67%)	2 / 15 (13.33%)	1 / 15 (6.67%)
occurrences (all)	2	2	1
Neutrophil count increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	3 / 15 (20.00%)
occurrences (all)	1	2	7
Red blood cell count decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Red blood cell count increased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin turgor decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Thyroxine free decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Thyroxine free increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Tri-iodothyronine free increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Weight increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	2 / 15 (13.33%)
occurrences (all)	0	2	6
White blood cell count increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Facial bones fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mouth injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Shunt malfunction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Stoma site discharge			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Tongue injury			

subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Vascular access complication subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 2	0 / 15 (0.00%) 0
Vascular access site discharge subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Vascular access site pain subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Vascular access site rash subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Wound subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Congenital, familial and genetic disorders Von Willebrand's disease subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0
Cardiac disorders Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Nervous system disorders Allodynia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0
Altered state of consciousness			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Amnesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Aphasia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Areflexia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Ataxia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	1	2
Balance disorder			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Consciousness fluctuating			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diplegia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Disturbance in attention			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	1	3
Dysarthria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Epilepsy			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Facial nerve disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haemorrhage intracranial			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 15 (13.33%)	7 / 15 (46.67%)	6 / 15 (40.00%)
occurrences (all)	2	10	9
Hemianopia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hemiparesis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hydrocephalus			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Hypersomnia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
IIIrd nerve disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Intracranial pressure increased			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Meningism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Motor dysfunction			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Muscle spasticity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Neuralgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Neuropathy peripheral			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Neurotoxicity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Paraparesis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Paresis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	4 / 15 (26.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	4	0	0
Somnolence			
subjects affected / exposed	3 / 15 (20.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	3	0	0
Speech disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Trigeminal nerve disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
VIIth nerve disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 15 (20.00%)	3 / 15 (20.00%)	3 / 15 (20.00%)
occurrences (all)	3	3	5

Coagulopathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	2
Lymphadenopathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Neutropenia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	3 / 15 (20.00%)
occurrences (all)	1	1	4
Pancytopenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Ear pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	1	3
Ear pruritus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Middle ear effusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Motion sickness			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Tympanic membrane perforation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Blindness			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	2	1
Dry eye			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	3
Eye haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1

Eye inflammation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Eye irritation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye movement disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Eye swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mydriasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	2
Photophobia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Pupillary reflex impaired subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Vision blurred subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	2 / 15 (13.33%) 2	3 / 15 (20.00%) 4
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Anal erythema subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Anal fissure subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Anal haemorrhage subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Anal incontinence subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0
Chronic gastritis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Colitis subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Constipation			

subjects affected / exposed	5 / 15 (33.33%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	5	0	4
Diarrhoea			
subjects affected / exposed	4 / 15 (26.67%)	4 / 15 (26.67%)	3 / 15 (20.00%)
occurrences (all)	4	6	3
Dry mouth			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Duodenal ulcer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Duodenitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	2 / 15 (13.33%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	3	2	0
Flatulence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	2 / 15 (13.33%)
occurrences (all)	0	1	2
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lip swelling			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	4 / 15 (26.67%)	1 / 15 (6.67%)	3 / 15 (20.00%)
occurrences (all)	4	1	6
Oral dysaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Post-tussive vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Proctalgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tongue oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Toothache			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 15 (26.67%)	4 / 15 (26.67%)	3 / 15 (20.00%)
occurrences (all)	5	6	8
Hepatobiliary disorders			
Hepatitis acute			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Angioedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Circumoral oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	0	0	5
Eczema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	3	1
Keratosis pilaris			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	3 / 15 (20.00%)
occurrences (all)	1	0	3
Rash			
subjects affected / exposed	2 / 15 (13.33%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	2	2	1
Rash erythematous			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	3 / 15 (20.00%) 3
Rash papular subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Rash pruritic subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Skin disorder subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0
Skin exfoliation subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Skin hypopigmentation subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Skin irritation subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Skin lesion subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Urticaria papular subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Xeroderma subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Renal and urinary disorders Dysuria			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Neurogenic bladder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Urinary hesitation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Urinary retention			
subjects affected / exposed	2 / 15 (13.33%)	2 / 15 (13.33%)	0 / 15 (0.00%)
occurrences (all)	2	2	0
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Diabetes insipidus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hyperthyroidism			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0

Hypothyroidism			
subjects affected / exposed	2 / 15 (13.33%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	2	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	1 / 15 (6.67%)
occurrences (all)	0	4	3
Arthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 15 (13.33%)	3 / 15 (20.00%)	2 / 15 (13.33%)
occurrences (all)	2	3	3
Dactylitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Mastication disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Muscular weakness			
subjects affected / exposed	3 / 15 (20.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	4	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	2
Musculoskeletal stiffness			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Neck pain			

subjects affected / exposed	0 / 15 (0.00%)	2 / 15 (13.33%)	1 / 15 (6.67%)
occurrences (all)	0	3	1
Osteopenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	1	1	1
Spinal pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Febrile infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Fungal skin infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis Escherichia coli			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Infection parasitic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Lip infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Pneumococcal infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	1	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Sepsis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0

Sinusitis bacterial subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Tooth abscess subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Metabolism and nutrition disorders			
Acidosis subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	3 / 15 (20.00%) 3	3 / 15 (20.00%) 3
Dehydration subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 2	0 / 15 (0.00%) 0
Fluid retention subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1
Hyperammonaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Hypercalcaemia subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 15 (0.00%) 0	0 / 15 (0.00%) 0
Hyperkalaemia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypernatraemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Hypochloraemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Hypoglycaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 15 (13.33%)	3 / 15 (20.00%)	0 / 15 (0.00%)
occurrences (all)	2	4	0
Hypomagnesaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 15 (6.67%)
occurrences (all)	0	1	1
Hyponatraemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	5
Hypophosphataemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Polydipsia			

subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Arm A4	Arm B4	Arm A5
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 12 (91.67%)	10 / 10 (100.00%)	18 / 19 (94.74%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Melanocytic naevus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Myelodysplastic syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Extremity necrosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Hypotension			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Application site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Device related thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Facial pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	5 / 19 (26.32%)
occurrences (all)	3	1	6
Gait disturbance			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
General physical health deterioration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Generalised oedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hypothermia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Influenza like illness			

subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	4 / 19 (21.05%)
occurrences (all)	1	0	4
Pyrexia			
subjects affected / exposed	3 / 12 (25.00%)	2 / 10 (20.00%)	2 / 19 (10.53%)
occurrences (all)	5	3	3
Sensation of foreign body			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Xerosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	1 / 12 (8.33%)	2 / 10 (20.00%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Infusion related hypersensitivity reaction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Seasonal allergy			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Reproductive system and breast disorders			
Testicular pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 12 (25.00%)	1 / 10 (10.00%)	4 / 19 (21.05%)
occurrences (all)	3	1	4
Dysphonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Hypoxia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Increased upper airway secretion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Nasal dryness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Behaviour disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 12 (8.33%)	2 / 10 (20.00%)	1 / 19 (5.26%)
occurrences (all)	1	2	1
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1

Dysphemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Irritability			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Mood swings			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Phonophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	4 / 19 (21.05%)
occurrences (all)	1	1	6
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anion gap increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	4 / 19 (21.05%)
occurrences (all)	1	2	7
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Blood bicarbonate increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood chloride decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatinine decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	2 / 19 (10.53%)
occurrences (all)	0	1	2
Blood lactate dehydrogenase decreased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Blood urea increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	3
Haematocrit decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Intestinal transit time increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	3 / 19 (15.79%)
occurrences (all)	1	1	6
Mean cell volume decreased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Mean cell volume increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Neutrophil count decreased subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 3	0 / 10 (0.00%) 0	3 / 19 (15.79%) 5
Neutrophil count increased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 3	0 / 10 (0.00%) 0	2 / 19 (10.53%) 2
Red blood cell count decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Red blood cell count increased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Skin turgor decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0
Thyroxine free decreased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Thyroxine free increased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Transaminases increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Tri-iodothyronine free increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0

White blood cell count decreased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2	0 / 10 (0.00%) 0	3 / 19 (15.79%) 9
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
White blood cells urine positive subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Contusion subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Facial bones fracture subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Fracture subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Head injury subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0
Mouth injury subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Procedural pain			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Shunt malfunction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Stoma site discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tongue injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vascular access complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vascular access site discharge			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Vascular access site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vascular access site rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Wound			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Von Willebrand's disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Sinus bradycardia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 10 (0.00%) 0	1 / 19 (5.26%) 2
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Tachycardia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Nervous system disorders			
Allodynia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Altered state of consciousness subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Amnesia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Aphasia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0
Areflexia subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Ataxia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Consciousness fluctuating subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Depressed level of consciousness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Diplegia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Disturbance in attention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Epilepsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Facial nerve disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Facial paralysis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Facial paresis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Haemorrhage intracranial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	5 / 12 (41.67%)	2 / 10 (20.00%)	13 / 19 (68.42%)
occurrences (all)	9	3	21
Hemianopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			

subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Hydrocephalus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypersomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
IIIrd nerve disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Intracranial pressure increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Meningism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Motor dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Nervous system disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Nystagmus			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Paraparesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Paresis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Partial seizures			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Seizure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	3
Somnolence			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Speech disorder			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Taste disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Trigeminal nerve disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vlth nerve disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	5 / 19 (26.32%)
occurrences (all)	4	0	5
Coagulopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Lymphadenopathy			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	2
Pancytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	3 / 19 (15.79%)
occurrences (all)	0	0	5

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Middle ear effusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blindness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Corneal epithelium defect			

subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Diplopia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Dry eye			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Eye discharge			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye movement disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eyelid function disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Mydriasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pupillary reflex impaired			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	5 / 19 (26.32%)
occurrences (all)	1	0	5
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anal erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Anal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Anal incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Chronic gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	1 / 12 (8.33%)	2 / 10 (20.00%)	5 / 19 (26.32%)
occurrences (all)	1	2	6
Diarrhoea			
subjects affected / exposed	3 / 12 (25.00%)	2 / 10 (20.00%)	3 / 19 (15.79%)
occurrences (all)	3	3	4
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Duodenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Gastric ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Loose tooth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 12 (33.33%)	1 / 10 (10.00%)	3 / 19 (15.79%)
occurrences (all)	5	1	5
Oral dysaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Post-tussive vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Proctalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Tongue oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 12 (41.67%)	4 / 10 (40.00%)	8 / 19 (42.11%)
occurrences (all)	9	4	15
Hepatobiliary disorders			
Hepatitis acute			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Angioedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Blister			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Circumoral oedema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Eczema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Keratosis pilaris			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Onychomadesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Petechiae			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0

Pruritus			
subjects affected / exposed	2 / 12 (16.67%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	2	0	2
Rash			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	2 / 19 (10.53%)
occurrences (all)	1	1	2
Rash papular			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Skin lesion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Urticaria papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Xeroderma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neurogenic bladder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oliguria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Urinary retention			

subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 2
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Diabetes insipidus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	2 / 12 (16.67%)	1 / 10 (10.00%)	1 / 19 (5.26%)
occurrences (all)	2	1	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Arthritis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Dactylitis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Mastication disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			

subjects affected / exposed	0 / 12 (0.00%)	1 / 10 (10.00%)	3 / 19 (15.79%)
occurrences (all)	0	1	3
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Osteopenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Spinal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Trismus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Catheter site infection			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0

Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Ear infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Enterobiasis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Eye infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Febrile infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Fungal skin infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Gastroenteritis Escherichia coli subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Infection parasitic subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	1 / 10 (10.00%) 1	0 / 19 (0.00%) 0
Lip infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0

Localised infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	3 / 19 (15.79%)
occurrences (all)	1	1	3
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Respiratory tract infection viral subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Rhinitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Sepsis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Sinusitis bacterial subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Tooth abscess subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 5	3 / 10 (30.00%) 3	3 / 19 (15.79%) 3
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	2 / 19 (10.53%) 2
Metabolism and nutrition disorders			
Acidosis subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	0 / 19 (0.00%) 0
Decreased appetite subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2	0 / 10 (0.00%) 0	4 / 19 (21.05%) 4
Dehydration subjects affected / exposed occurrences (all)	0 / 12 (0.00%) 0	0 / 10 (0.00%) 0	1 / 19 (5.26%) 1
Fluid retention			

subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperammonaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	3
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	3 / 19 (15.79%)
occurrences (all)	0	0	3
Hypochloraemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypokalaemia			

subjects affected / exposed	1 / 12 (8.33%)	1 / 10 (10.00%)	5 / 19 (26.32%)
occurrences (all)	1	1	13
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	1 / 12 (8.33%)	0 / 10 (0.00%)	2 / 19 (10.53%)
occurrences (all)	2	0	2
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	6 / 19 (31.58%)
occurrences (all)	0	0	9
Polydipsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 10 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Arm B5		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 19 (94.74%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Melanocytic naevus			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Myelodysplastic syndrome			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Bloody discharge			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Embolism			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Extremity necrosis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Flushing			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
General disorders and administration site conditions			
Application site pruritus			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Asthenia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Device related thrombosis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Facial pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	4 / 19 (21.05%)		
occurrences (all)	6		
Gait disturbance			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
General physical health deterioration			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Generalised oedema			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypothermia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Mucosal inflammation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Pyrexia			
subjects affected / exposed	5 / 19 (26.32%)		
occurrences (all)	7		
Sensation of foreign body			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Xerosis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Immune system disorders			

Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0		
Hypersensitivity subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1		
Infusion related hypersensitivity reaction subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0		
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0		
Reproductive system and breast disorders			
Testicular pain subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0		
Vaginal haemorrhage subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1		
Respiratory, thoracic and mediastinal disorders			
Bronchospasm subjects affected / exposed occurrences (all)	2 / 19 (10.53%) 3		
Cough subjects affected / exposed occurrences (all)	6 / 19 (31.58%) 9		
Dysphonia subjects affected / exposed occurrences (all)	0 / 19 (0.00%) 0		
Dyspnoea subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1		
Epistaxis subjects affected / exposed occurrences (all)	1 / 19 (5.26%) 1		

Hypoxia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Increased upper airway secretion			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Nasal dryness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Productive cough			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Rhinorrhoea			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sneezing			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Tachypnoea			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Behaviour disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Dysphemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Irritability			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Mood swings			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Phonophobia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Restlessness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Suicidal ideation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Amylase increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Anion gap increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood bicarbonate increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood chloride decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood creatine increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood creatinine decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood magnesium decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood sodium increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood thyroid stimulating hormone increased			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Blood urea increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood uric acid increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Haematocrit decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Intestinal transit time increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Liver function test increased			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Lymphocyte count decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Mean cell volume decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Mean cell volume increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Neutrophil count increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Red blood cell count decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Red blood cell count increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Skin turgor decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Thyroxine free decreased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Thyroxine free increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Transaminases increased			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Tri-iodothyronine free increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Weight increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
White blood cell count increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
White blood cells urine positive			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Facial bones fracture			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Fracture			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Head injury			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Mouth injury			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Shunt malfunction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Stoma site discharge			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Tongue injury			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vascular access complication			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vascular access site discharge			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vascular access site pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vascular access site rash			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Wound			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Von Willebrand's disease			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Allodynia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Altered state of consciousness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Aphasia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Areflexia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Ataxia			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Balance disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Consciousness fluctuating			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Depressed level of consciousness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Diplegia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Disturbance in attention			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Dysarthria			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Epilepsy			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Facial nerve disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Facial paralysis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Facial paresis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Haemorrhage intracranial			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	5 / 19 (26.32%)		
occurrences (all)	7		
Hemianopia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hemiparesis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hydrocephalus			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypersomnia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
IIIrd nerve disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Intracranial pressure increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Meningism			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Motor dysfunction			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Muscle spasticity			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Nervous system disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Neuralgia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Neurotoxicity			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Nystagmus			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Paraparesis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Paresis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Partial seizures			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Presyncope			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Seizure			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	3		
Somnolence			

subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Speech disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Taste disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Trigeminal nerve disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vlth nerve disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Coagulopathy			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Leukopenia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

Neutropenia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Pancytopenia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Ear pruritus			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Middle ear effusion			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Motion sickness			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Tinnitus			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Eye disorders			

Blepharospasm			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Blindness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Conjunctival hyperaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Corneal epithelium defect			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Diplopia			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Dry eye			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eye discharge			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eye haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eye inflammation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eye irritation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eye movement disorder			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Eye pain			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		

Eye swelling			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Eyelid function disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eyelid oedema			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Eyelid ptosis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Mydriasis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Ocular hyperaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Photophobia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Pupillary reflex impaired			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Abdominal pain			

subjects affected / exposed	4 / 19 (21.05%)		
occurrences (all)	5		
Abdominal pain upper			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Anal erythema			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Anal fissure			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Anal haemorrhage			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Anal incontinence			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Chronic gastritis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Colitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	4 / 19 (21.05%)		
occurrences (all)	5		
Diarrhoea			
subjects affected / exposed	5 / 19 (26.32%)		
occurrences (all)	5		
Dry mouth			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Duodenal ulcer			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Duodenitis			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Gastric ulcer			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Gastritis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Immune-mediated enterocolitis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Lip swelling			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Loose tooth			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	5 / 19 (26.32%)		
occurrences (all)	5		
Oral dysaesthesia			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Paraesthesia oral			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Periodontal disease			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Post-tussive vomiting			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Proctalgia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Salivary hypersecretion			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Tongue oedema			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	10 / 19 (52.63%)		
occurrences (all)	20		
Hepatobiliary disorders			
Hepatitis acute			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Alopecia			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Angioedema			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Blister			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Circumoral oedema			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Decubitus ulcer			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Dermatitis diaper			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Dry skin			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eczema			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Keratosis pilaris			

subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Onychomadesis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Rash erythematous			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Rash macular			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Rash papular			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Skin disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

Skin exfoliation			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		
Skin hypopigmentation			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Skin irritation			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Skin lesion			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Urticaria papular			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Xeroderma			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Micturition urgency			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Neurogenic bladder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Nocturia			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Oliguria			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Urinary hesitation			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Urinary retention			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Endocrine disorders			
Cushingoid			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Diabetes insipidus			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hyperthyroidism			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Hypothyroidism			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Arthritis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Back pain			

subjects affected / exposed	4 / 19 (21.05%)		
occurrences (all)	4		
Dactylitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Mastication disorder			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	2 / 19 (10.53%)		
occurrences (all)	2		
Osteopenia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Spinal pain			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Torticollis			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Trismus			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Catheter site infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Clostridium difficile infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Enterobiasis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Eye infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Febrile infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Fungal skin infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Gastroenteritis Escherichia coli			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

Herpes zoster			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Infection parasitic			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Lip infection			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Localised infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Otitis externa			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Paronychia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Pneumococcal infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

Pneumonia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Postoperative wound infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Respiratory tract infection viral			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sepsis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Sinusitis bacterial			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Tooth abscess			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	2		
Urinary tract infection			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

Metabolism and nutrition disorders			
Acidosis			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Decreased appetite			
subjects affected / exposed	3 / 19 (15.79%)		
occurrences (all)	4		
Dehydration			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Fluid retention			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hyperammonaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Hypercalcaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hyperglycaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypernatraemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypertriglyceridaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			

subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypochloraemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	1 / 19 (5.26%)		
occurrences (all)	1		
Hypomagnesaemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		
Polydipsia			
subjects affected / exposed	0 / 19 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported