Clinical trial results:
A Phase 1 Study of the TRK Inhibitor Selitrectinib (BAY 2731954) in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Summary

EudraCT number	2017-004246-20
Trial protocol	DK FR DE ES GB IE IT BE
Global end of trial date	30 January 2023

Results information

Result version number	v1 (current)
This version publication date	30 July 2023
First version publication date	30 July 2023

Trial information

Trial identification

Sponsor protocol code	20810

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03215511
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bayer AG
Sponsor organisation address	Kaiser-Wilhelm-Allee, Leverkusen, Germany, D-51368
Public contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com
Scientific contact	Therapeutic Area Head, Bayer AG, clinical-trials-contact@bayer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 January 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 January 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to determine the recommended dose for further study of oral selitrectinib in 2 patient groups with previously treated neurotrophic tyrosine receptor kinase (NTRK) fusion cancers defined as age 12 years and older and age <12 years.
The secondary objectives of this study were:
• To characterize the pharmacokinetic (PK) properties of selitrectinib.
• To characterize the safety and tolerability of selitrectinib.
• To assess objective response rate (ORR) according to best response by Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1) as determined by investigator, in patients with a documented NTRK fusion cancer previously treated with a tropomyosin receptor kinase (TRK) inhibitor.
• To assess ORR according to best response by Response Assessment in Neuro-Oncology (RANO), as determined by investigator, in patients with primary central nervous system (CNS) malignancies with NTRK fusion.

Protection of trial subjects:

The conduct of this clinical study met all local legal and regulatory requirements. The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and the International Conference on Harmonization guideline E6: Good Clinical Practice. Before entering the study, the informed consent form was read by and explained to all subjects and/or their legally authorized representative. Participating subjects and/or their legally authorized representative signed informed consent form and could withdraw from the study at any time without any disadvantage and without having to provide a reason for this decision. Only investigators qualified by training and experience were selected as appropriate experts to investigate the study drug.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 July 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	Belgium: 1
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	Austria: 1
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Ireland: 1
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Singapore: 2
Country: Number of subjects enrolled	Spain: 7

Country: Number of subjects enrolled	United States: 58
Worldwide total number of subjects	81
EEA total number of subjects	21

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)	1
Children (2-11 years)	10
Adolescents (12-17 years)	4
Adults (18-64 years)	54
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This multinational study was conducted at 42 centers of 13 countries from 03-Jul-2017 (first patient first visit) to 30-Jan-2023 (last patient last visit)

Pre-assignment

Screening details:

A total of 91 patients were enrolled in the study. Of these, there were 10 screen failures, and 81 patients received at least 1 dose of study drug.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Capsule Cohort 1

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg twice daily (BID), in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

100 mg, Twice daily (BID)

Arm title	Capsule Cohort 2

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 150 mg twice daily (BID), in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

150 mg, Twice daily (BID)

Arm title	Capsule Cohort 3

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg once daily (QD), in continuous 28-day cycles.

Arm type	Experimental

Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

100 mg, Once daily (QD)

Arm title	Capsule Cohort 4

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg once daily (QD), in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

50 mg, Once daily (QD)

Arm title	Capsule Cohort 5a

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 75 mg BID, in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

50 mg QD with escalation every 14 days to 75 mg BID (capsule)

Arm title	Capsule Cohort 5b

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 150 mg QD, in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

50 mg QD with escalation every 14 days to 150 mg QD

Arm title	Suspension Cohort 6a

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg BID, in continuous 28-day cycles.

Arm type	Experimental

Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

50mg BID (liquid suspension)

Arm title	Suspension Cohort 6b

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 75mg BID, in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

75 mg BID (liquid suspension)

Arm title	Suspension Cohort 7a

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg QD with escalation after 7 days to 50mg BID, in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

50mg QD with escalation after 7 days to 50mg BID

Arm title	Suspension Cohort 7b

Arm description:

Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg QD for 7 days, then 50mg BID for 7 days, then 75mg BID, in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

50mg QD for 7 days, then 50mg BID, for 7 days, then 75mg BID

Arm title	Pediatric Cohort 43 mg/m^2 BID

Arm description:

Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 43 mg/m^2 BID, in continuous 28-day cycles.

Arm type	Experimental

Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

75 mg BID

Arm title	Pediatric Cohort 58 mg/m^2 BID

Arm description:

Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 58 mg/m^2 BID, in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

100 mg BID

Arm title	Pediatric Cohort 87 mg/m^2 BID

Arm description:

Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 87 mg/m^2 BID, in continuous 28-day cycles.

Arm type	Experimental
Investigational medicinal product name	Selitrectinib
Investigational medicinal product code	BAY2731954
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

150 mg BID

Number of subjects in period 1	Capsule Cohort 1	Capsule Cohort 2	Capsule Cohort 3
Started	5	2	2
Completed	0	0	0
Not completed	5	2	2
Adverse event, serious fatal	4	2	1
Consent withdrawn by subject	1	-	-
Other	-	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Capsule Cohort 4	Capsule Cohort 5a	Capsule Cohort 5b
Started	8	23	3
Completed	0	0	0
Not completed	8	23	3
Adverse event, serious fatal	7	18	3

Consent withdrawn by subject	1	3	-
Other	-	2	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Suspension Cohort 6a	Suspension Cohort 6b	Suspension Cohort 7a
Started	3	4	14
Completed	0	0	0
Not completed	3	4	14
Adverse event, serious fatal	2	2	9
Consent withdrawn by subject	1	1	3
Other	-	-	2
Lost to follow-up	-	1	-

Number of subjects in period 1	Suspension Cohort 7b	Pediatric Cohort 43 mg/m^2 BID	Pediatric Cohort 58 mg/m^2 BID
Started	6	6	4
Completed	0	0	0
Not completed	6	6	4
Adverse event, serious fatal	3	4	2
Consent withdrawn by subject	-	-	-
Other	3	2	2
Lost to follow-up	-	-	-

Number of subjects in period 1	Pediatric Cohort 87 mg/m^2 BID
Started	1
Completed	0
Not completed	1
Adverse event, serious fatal	-
Consent withdrawn by subject	-
Other	-
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	Capsule Cohort 1
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg twice daily (BID), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 2
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 150 mg twice daily (BID), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 3
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg once daily (QD), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 4
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg once daily (QD), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 5a
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 75 mg BID, in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 5b
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 150 mg QD, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 6a
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg BID, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 6b
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 75mg BID, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 7a
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg QD with escalation after 7 days to 50mg BID, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 7b
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg QD for 7 days, then 50mg BID for 7 days, then 75mg BID, in continuous 28-day cycles.	
Reporting group title	Pediatric Cohort 43 mg/m^2 BID
Reporting group description:	
Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 43 mg/m^2 BID, in continuous 28-day cycles.	
Reporting group title	Pediatric Cohort 58 mg/m^2 BID
Reporting group description:	
Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 58 mg/m^2 BID, in continuous 28-day cycles.	
Reporting group title	Pediatric Cohort 87 mg/m^2 BID
Reporting group description:	
Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid	

Reporting group values	Capsule Cohort 1	Capsule Cohort 2	Capsule Cohort 3
Number of subjects	5	2	2
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
median	55.0	53.0	59.5
full range (min-max)	47 to 64	48 to 58	48 to 71
Gender Categorical Units: Subjects			
Female	2	1	2
Male	3	1	0

Reporting group values	Capsule Cohort 4	Capsule Cohort 5a	Capsule Cohort 5b
Number of subjects	8	23	3
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
median	34.5	51.0	48.0
full range (min-max)	13 to 58	18 to 76	14 to 51
Gender Categorical Units: Subjects			
Female	7	9	2
Male	1	14	1

Reporting group values	Suspension Cohort 6a	Suspension Cohort 6b	Suspension Cohort 7a
Number of subjects	3	4	14
Age Categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous Units: years			
median	56.0	48.0	47.0
full range (min-max)	53 to 58	29 to 69	17 to 75
Gender Categorical Units: Subjects			
Female	1	1	7
Male	2	3	7

Reporting group values	Suspension Cohort 7b	Pediatric Cohort 43 mg/m^2 BID	Pediatric Cohort 58 mg/m^2 BID
Number of subjects	6	6	4
Age Categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous Units: years			
median	56.5	5.5	6.0
full range (min-max)	38 to 73	1 to 9	5 to 10
Gender Categorical Units: Subjects			
Female	2	2	2
Male	4	4	2

Reporting group values	Pediatric Cohort 87 mg/m^2 BID	Total	
Number of subjects	1	81	

Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age Continuous Units: years			
median	2.0		
full range (min-max)	2 to 2	-	
Gender Categorical Units: Subjects			
Female	0	38	
Male	1	43	

End points

End points reporting groups

Reporting group title	Capsule Cohort 1
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg twice daily (BID), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 2
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 150 mg twice daily (BID), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 3
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg once daily (QD), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 4
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg once daily (QD), in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 5a
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 75 mg BID, in continuous 28-day cycles.	
Reporting group title	Capsule Cohort 5b
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 150 mg QD, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 6a
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg BID, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 6b
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 75mg BID, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 7a
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg QD with escalation after 7 days to 50mg BID, in continuous 28-day cycles.	
Reporting group title	Suspension Cohort 7b
Reporting group description:	
Subjects aged ≥12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg QD for 7 days, then 50mg BID for 7 days, then 75mg BID, in continuous 28-day cycles.	
Reporting group title	Pediatric Cohort 43 mg/m^2 BID
Reporting group description:	
Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 43 mg/m^2 BID, in continuous 28-day cycles.	
Reporting group title	Pediatric Cohort 58 mg/m^2 BID
Reporting group description:	
Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 58 mg/m^2 BID, in continuous 28-day cycles.	
Reporting group title	Pediatric Cohort 87 mg/m^2 BID
Reporting group description:	
Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid	

suspension 87 mg/m^2 BID, in continuous 28-day cycles.

Subject analysis set title	DLT Analysis Set (subjects aged 12 years and older)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The DLT Analysis Set (DLT) included all patients enrolled in the dose escalation part who experienced a DLT within the DLT period, and those without a DLT who had completed the safety assessments through the assigned DLT period and had received at least 75% of the planned total dose during Cycle 1.

Subject analysis set title	DLT Analysis Set (subjects aged less than 12 years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The DLT Analysis Set (DLT) included all patients enrolled in the dose escalation part who experienced a DLT within the DLT period, and those without a DLT who had completed the safety assessments through the assigned DLT period and had received at least 75% of the planned total dose during Cycle 1.

Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All enrolled participants who received 1 or more doses of selitrectinib were included in the Safety Analysis Set

Subject analysis set title	Participants with primary CNS tumors
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants with primary CNS tumors evaluated via RANO

Primary: Maximum tolerated dose (MTD) / recommended dose in patients age 12 years and older and age < 12 years

End point title	Maximum tolerated dose (MTD) / recommended dose in patients age 12 years and older and age < 12 years[1]

End point description:

The MTD for either age group was defined as the dose level immediately below that in which 2 or more patients experienced a DLT during the assigned DLT period. In table below, w stands for "week", f/b stands for "followed by"

End point type	Primary

End point timeframe:

For patients age 12 years and older: dose-limiting toxicity (DLT) period was up to 42 days; For patients age less than 12 years old: DLT period was 28 days or completion of cycle 1.

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: The analysis for this endpoint is descriptive.

End point values	DLT Analysis Set (subjects aged 12 years and older)	DLT Analysis Set (subjects aged less than 12 years)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29[2]	7[3]		
Units: mg QD				
number (not applicable)	50	99999		

Notes:

[2] - MTD was either 50mg QD for 1 w, f/b 50mg BID for 1 w, f/b 75mg BID or 50mg BID for 1 w f/b 75mg BID
[3] - "99999" stands for not determined, as there were no DLTs in this age group.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with TEAE and their severity

End point title	Number of participants with TEAE and their severity

End point description:

Treatment emergent adverse events (TEAEs) was defined as AEs that start on or after the first administration of study drug. TEAE were collected up to 28 ± 7 days post last dose.

End point type	Secondary

End point timeframe:

From start of the first administration of study drug, up to 28 ± 7 days post last dose

End point values	Capsule Cohort 1	Capsule Cohort 2	Capsule Cohort 3	Capsule Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	2	8
Units: subjects				
Any TEAEs	5	2	2	8
Serious TEAEs	3	1	1	5
Maximum Severity Grade ≥3	3	2	2	6

End point values	Capsule Cohort 5a	Capsule Cohort 5b	Suspension Cohort 6a	Suspension Cohort 6b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	3	3	4
Units: subjects				
Any TEAEs	23	3	3	4
Serious TEAEs	16	1	0	4
Maximum Severity Grade ≥3	18	1	1	4

End point values	Suspension Cohort 7a	Suspension Cohort 7b	Pediatric Cohort 43 mg/m^2 BID	Pediatric Cohort 58 mg/m^2 BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	6	6	4
Units: subjects				
Any TEAEs	14	6	6	4
Serious TEAEs	8	2	3	3
Maximum Severity Grade ≥3	12	2	4	3

End point values	Pediatric Cohort 87 mg/m^2 BID			

Subject group type	Reporting group			
Number of subjects analysed	1			
Units: subjects				
Any TEAEs	1			
Serious TEAEs	0			
Maximum Severity Grade ≥3	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with treatment related TEAE

End point title	Number of participants with treatment related TEAE

End point description:

The causal relationship between the occurrence of TEAE and study drug was judged by the Investigator, based on the conventions described in protocol

End point type	Secondary

End point timeframe:

Treatment emergent adverse events (TEAEs) was defined as AEs that start on or after the first administration of study drug. TEAE were collected up to 28 ± 7 days post last dose.

End point values	Capsule Cohort 1	Capsule Cohort 2	Capsule Cohort 3	Capsule Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	2	8
Units: subjects				
Any TEAEs	5	2	2	8
Serious TEAEs	0	0	0	0
Maximum Severity Grade ≥3	0	2	1	1

End point values	Capsule Cohort 5a	Capsule Cohort 5b	Suspension Cohort 6a	Suspension Cohort 6b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	3	3	4
Units: subjects				
Any TEAEs	18	3	2	4
Serious TEAEs	0	0	0	2
Maximum Severity Grade ≥3	5	1	1	2

End point values	Suspension Cohort 7a	Suspension Cohort 7b	Pediatric Cohort 43 mg/m^2 BID	Pediatric Cohort 58 mg/m^2 BID

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	6	6	4
Units: subjects				
Any TEAEs	13	6	5	4
Serious TEAEs	1	0	1	1
Maximum Severity Grade ≥3	6	0	2	2

End point values	Pediatric Cohort 87 mg/m^2 BID			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: subjects				
Any TEAEs	1			
Serious TEAEs	0			
Maximum Severity Grade ≥3	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with hematology shifts from normal baseline value

End point title	Number of participants with hematology shifts from normal baseline value

End point description:

Directional shifts from baseline according to normal range are summarized for hematology parameters for the Safety Analysis Set. LLN: lower limit of normal; ULN = upper limit of normal

End point type	Secondary

End point timeframe:

Up to 56 months

End point values	Safety Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	81[4]			
Units: subjects				
Basophils Count below LLN	0			
Basophils Count Above ULN	3			
Eosinophils Count Below LLN	7			
Eosinophils Count Above ULN	7			
Monocytes Count Below LLN	9			
Monocytes Count Above ULN	7			
Hematocrit Below LLN	19			
Hematocrit Above ULN	3			

Red Blood Cell Count Below LLN	10			
Red Blood Cell Count Above ULN	8			

Notes:

[4] - Only subjects with baseline assessment and at least one post-baseline assessment were included

Statistical analyses

No statistical analyses for this end point

Secondary: Number participants with chemistry shifts from baseline according to normal range

End point title	Number participants with chemistry shifts from baseline according to normal range

End point description:

Directional shifts from baseline according to normal range are summarized for chemistry parameters for the Safety Analysis Set. A baseline measurement and at least 1 laboratory or other safety-related measurement obtained after at least 1 dose of study drug was required for inclusion in the analysis of a specific parameter.

End point type	Secondary

End point timeframe:

up to 56 months

End point values	Safety Analysis Set			
Subject group type	Subject analysis set			
Number of subjects analysed	81			
Units: subjects				
Blood Urea Nitrogen Below LLN	3			
Blood Urea Nitrogen Above ULN	18			
Lactate Dehydrogenase Below LLN	3			
Lactate Dehydrogenase Above ULN	25			
Total Protein Below LLN	17			
Total Protein Above ULN	5			
Chloride Below LLN	9			
Chloride Above ULN	34			
Calcium Below LLN	19			
Calcium Above ULN	9			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate as determined by the Investigator in participants with a documented NTRK fusion cancer previously treated with a TRK inhibitor

End point title	Objective Response Rate as determined by the Investigator in participants with a documented NTRK fusion cancer previously

	treated with a TRK inhibitor

End point description:

Objective Response Rate (ORR) was defined as the proportion of patients with a BOR of confirmed CR, or PR. Response was confirmed by a repeat assessment no less than 28 days later.

End point type	Secondary

End point timeframe:

up to 56 months

End point values	Capsule Cohort 1	Capsule Cohort 2	Capsule Cohort 3	Capsule Cohort 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	2	8
Units: Percent (%)				
number (confidence interval 95%)	20 (0.5 to 71.6)	0 (0.0 to 84.2)	50 (1.3 to 98.7)	37.5 (8.5 to 75.5)

End point values	Capsule Cohort 5a	Capsule Cohort 5b	Suspension Cohort 6a	Suspension Cohort 6b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	3	3	4
Units: Percent (%)				
number (confidence interval 95%)	13.0 (2.8 to 33.6)	33.3 (0.8 to 90.6)	33.3 (0.8 to 90.6)	0 (0.0 to 60.2)

End point values	Suspension Cohort 7a	Suspension Cohort 7b	Pediatric Cohort 43 mg/m^2 BID	Pediatric Cohort 58 mg/m^2 BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	6	6	4
Units: Percent (%)				
number (confidence interval 95%)	14.3 (1.8 to 42.8)	50.0 (11.8 to 88.2)	33.3 (4.3 to 77.7)	25.0 (0.6 to 80.6)

End point values	Pediatric Cohort 87 mg/m^2 BID			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percent (%)				
number (confidence interval 95%)	0 (0.0 to 97.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 1 Day 1

End point title	Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 1 Day 1[5]

End point description:

"99999" in data entry fields stands for "Not Calculated"

End point type	Secondary

End point timeframe:

Cycle 1 Day 1

Notes:

[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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 1	Capsule Cohort 2	Suspension Cohort 6a	Suspension Cohort 6b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	2	3	4
Units: ng/mL				
geometric mean (geometric coefficient of variation)	182 (± 60.9)	69.1 (± 87.8)	145 (± 13.5)	206 (± 74.0)

End point values	Pediatric Cohort 43 mg/m^2 BID	Pediatric Cohort 58 mg/m^2 BID	Pediatric Cohort 87 mg/m^2 BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	4	1[6]	
Units: ng/mL				
geometric mean (geometric coefficient of variation)	228 (± 80.2)	167 (± 72.9)	181 (± 99999)	

Notes:

[6] - "99999" in data entry fields stands for "Not Calculated"

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate as determined by investigator in participants with primary CNS malignancies

End point title	Objective Response Rate as determined by investigator in participants with primary CNS malignancies

End point description:

primary CNS tumors were evaluated via Response Assessment in Neuro-Oncology (RANO)

End point type	Secondary

End point timeframe:

Objective Response Rate (%) is defined as the proportion of patients with Best Overall Response of confirmed CR, or PR. Response was confirmed by a repeat assessment no less than 28 days.

End point values	Participants with primary CNS tumors			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: percent (%)				
number (confidence interval 95%)	28.6 (8.4 to 58.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 1 Day 8

End point title	Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 1 Day 8[7]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 8

Notes:

[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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 1	Suspension Cohort 7a	Suspension Cohort 7b	Pediatric Cohort 43 mg/m^2 BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	10	6	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)	150 (± 62.1)	161 (± 58.3)	136 (± 57.8)	274 (± 41.8)

End point values	Pediatric Cohort 58 mg/m^2 BID			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	229 (± 37.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 1 Day 15

End point title	Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 1 Day 15[8]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 15

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 5a	Capsule Cohort 5b	Suspension Cohort 6a	Suspension Cohort 6b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	3	2	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)	159 (± 93.3)	244 (± 46.7)	119 (± 3.6)	101 (± 41.6)

End point values	Suspension Cohort 7b	Pediatric Cohort 58 mg/m^2 BID		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	2		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	198 (± 48.1)	354 (± 41.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve of BAY2731954 in plasma for BID dosing, Cycle 1 Day 1

End point title	Area under the concentration versus time curve of BAY2731954

	in plasma for BID dosing, Cycle 1 Day 1[9]

End point description:

"99999" in data entry fields stands for "Not Calculated"

End point type	Secondary

End point timeframe:

Cycle 1 Day 1

Notes:

[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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 1	Capsule Cohort 2	Suspension Cohort 6a	Suspension Cohort 6b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	1[10]	3	4
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-10)	527 (± 85.0)	525 (± 99999)	380 (± 15.3)	459 (± 57.2)
AUC(0-12)	537 (± 87.3)	538 (± 99999)	384 (± 15.6)	464 (± 57.0)

Notes:

[10] - "99999" in data entry fields stands for "Not Calculated"

End point values	Pediatric Cohort 43 mg/m^2 BID	Pediatric Cohort 58 mg/m^2 BID	Pediatric Cohort 87 mg/m^2 BID	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	2	1[11]	
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-10)	492 (± 60.5)	243 (± 57.5)	229 (± 99999)	
AUC(0-12)	493 (± 60.5)	243 (± 57.5)	229 (± 99999)	

Notes:

[11] - "99999" in data entry fields stands for "Not Calculated"

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve of BAY2731954 in plasma for BID dosing, Cycle 1 Day 8

End point title	Area under the concentration versus time curve of BAY2731954 in plasma for BID dosing, Cycle 1 Day 8[12]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 8

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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 1	Capsule Cohort 5a	Suspension Cohort 7a	Suspension Cohort 7b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	19	10	6
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-10)	593 (± 120.4)	459 (± 101.4)	401 (± 48.2)	389 (± 51.1)
AUC(0-12)	638 (± 135.6)	500 (± 100.7)	406 (± 48.5)	394 (± 51.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve of BAY2731954 in plasma for BID dosing, Cycle 1 Day 15

End point title	Area under the concentration versus time curve of BAY2731954 in plasma for BID dosing, Cycle 1 Day 15[13]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 15

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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 5a	Suspension Cohort 6a	Suspension Cohort 6b	Suspension Cohort 7b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	2	3	5
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-10)	454 (± 89.7)	320 (± 4.1)	287 (± 49.5)	558 (± 57.4)
AUC(0-12)	470 (± 91.4)	338 (± 3.0)	295 (± 50.3)	575 (± 60.5)

End point values	Pediatric Cohort 58 mg/m^2 BID			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: h*ng/mL				

geometric mean (geometric coefficient of variation)				
AUC(0-10) AUC(0-12)	436 (± 171) 449 (± 177.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 1 Day 1

End point title	Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 1 Day 1[14]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1

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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 3	Capsule Cohort 4	Capsule Cohort 5a	Capsule Cohort 5b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	6	20	2
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	470 (± 37.3)	435 (± 173.5)	385 (± 105.7)	197 (± 27.6)

End point values	Suspension Cohort 7a	Suspension Cohort 7b		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	6		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	318 (± 39.7)	366 (± 42.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 1 Day 15

End point title	Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 1 Day 15[15]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 15

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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 5b			
Subject group type	Reporting group			
Number of subjects analysed	3			
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	907 (± 50.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 1 Day 8

End point title	Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 1 Day 8[16]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 8

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: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 3	Capsule Cohort 4	Capsule Cohort 5a	Capsule Cohort 5b
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[17]	7	19	3
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	543 (± 99999)	801 (± 98.9)	618 (± 99.5)	514 (± 101.6)

Notes:

[17] - "99999" in data entry fields stands for "Not Calculated"

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 2 Day 1

End point title	Area under the concentration versus time curve AUC(0-24) of BAY2731954 in plasma for QD dosing, Cycle 2 Day 1[18]

End point description:

End point type	Secondary

End point timeframe:

Cycle 2 Day 1

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 5b			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)	761 (± 59.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the concentration versus time curve of BAY2731954 in plasma for BID dosing, Cycle 2 Day 1

End point title	Area under the concentration versus time curve of BAY2731954 in plasma for BID dosing, Cycle 2 Day 1[19]

End point description:

End point type	Secondary

End point timeframe:

Cycle 2 Day 1

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 5a			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
AUC(0-10)	504 (± 123.5)			
AUC(0-12)	520 (± 124.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 2 Day 1

End point title	Maximum concentration (Cmax) of BAY2731954 in plasma for BID dosing, Cycle 2 Day 1[20]

End point description:

End point type	Secondary

End point timeframe:

Cycle 2 Day 1

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting PK data of arms with certain dosage schedule on certain day.

End point values	Capsule Cohort 5a			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	169 (± 135.4)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

TEAEs was defined as AEs that start on or after the first administration of study drug, TEAEs were collected up to 28 +/- 7 days post last dose.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Capsule Cohort 2

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) capsule 150 mg twice daily (BID), in continuous 28-day cycles.

Reporting group title	Capsule Cohort 1

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg twice daily (BID), in continuous 28-day cycles.

Reporting group title	Capsule Cohort 3

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) capsule 100 mg once daily (QD), in continuous 28-day cycles.

Reporting group title	Capsule Cohort 4

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg once daily (QD), in continuous 28-day cycles.

Reporting group title	Capsule Cohort 5a

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 75 mg BID, in continuous 28-day cycles.

Reporting group title	Capsule Cohort 5b

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) capsule 50 mg QD with escalation every 14 days to 150 mg QD, in continuous 28-day cycles.

Reporting group title	Pediatric Cohort 87 mg/mm^2 BID

Reporting group description:

Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 87 mg/m^2 BID, in continuous 28-day cycles.

Reporting group title	Suspension Cohort 6b

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 75mg BID, in continuous 28-day cycles.

Reporting group title	Suspension Cohort 7b

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50 mg BID for 7 days, then 75 mg BID for 7 days, then 100 mg BID, in continuous 28-day cycles.

Reporting group title	Suspension Cohort7a

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50 mg BID with escalation after 7 days to 75 mg BID, in continuous 28-day cycles.

Reporting group title	Pediatric Cohort 58 mg/mm^2 BID

Reporting group description:

Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 58 mg/m^2 BID, in continuous 28-day cycles.

Reporting group title	Pediatric Cohort 43 mg/mm^2 BID

Reporting group description:

Subjects aged < 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 43 mg/m^2 BID, in continuous 28-day cycles.

Reporting group title	Suspension Cohort 6a

Reporting group description:

Subjects aged >= 12 years in this group were administrated with selitrectinib (BAY2731954) liquid suspension 50mg BID, in continuous 28-day cycles.

Serious adverse events	Capsule Cohort 2	Capsule Cohort 1	Capsule Cohort 3
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	3 / 5 (60.00%)	1 / 2 (50.00%)
number of deaths (all causes)	2	4	1
number of deaths resulting from adverse events	1	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood glucose increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Facial paralysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Capsule Cohort 4	Capsule Cohort 5a	Capsule Cohort 5b
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 8 (62.50%)	16 / 23 (69.57%)	1 / 3 (33.33%)
number of deaths (all causes)	7	18	3
number of deaths resulting from adverse events	4	7	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stromal tumour			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration			

site conditions			
Asthenia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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
Cyst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 8 (12.50%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 3	0 / 0
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Disease progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (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
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (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
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood glucose increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Overdose			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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
Atrial fibrillation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Facial paralysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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
Hydrocephalus			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			

subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Ascites			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (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
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal colic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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
Bursitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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

Septic shock			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (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
Metabolism and nutrition disorders			

Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Pediatric Cohort 87 mg/mm^2 BID	Suspension Cohort 6b	Suspension Cohort 7b
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	4 / 4 (100.00%)	2 / 6 (33.33%)
number of deaths (all causes)	0	2	3
number of deaths resulting from adverse events	0	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 stromal tumour			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Death			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	0 / 6 (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
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Blood glucose increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Overdose			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Femoral neck fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Skull fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Facial paralysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Depressed level of consciousness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 paresis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Ascites			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 haemorrhage			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 colic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 viral			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (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

Serious adverse events	Suspension	Pediatric Cohort 58	Pediatric Cohort 43

	Cohort7a	mg/mm^2 BID	mg/mm^2 BID
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 14 (57.14%)	3 / 4 (75.00%)	3 / 6 (50.00%)
number of deaths (all causes)	9	2	4
number of deaths resulting from adverse events	3	1	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 stromal tumour			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal squamous cell carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			

subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyst			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease progression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	2 / 14 (14.29%)	0 / 4 (0.00%)	0 / 6 (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 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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 failure			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Investigations			

Blood glucose increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Tracheal obstruction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Skull fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Procedural pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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

Sinus bradycardia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Facial paralysis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Dysarthria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Depressed level of consciousness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Coma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Headache			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Hydrocephalus			

subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hepatic encephalopathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Seizure			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Brain oedema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Facial paresis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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
Syncope			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	0 / 6 (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
Cognitive disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 colic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (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 pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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			
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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	2 / 14 (14.29%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Septic shock			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoalbuminaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
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	Suspension Cohort 6a		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioblastoma			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tumour haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal stromal tumour			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neuroendocrine carcinoma				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metastases to central nervous system				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal squamous cell carcinoma				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Hypotension				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Asthenia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cyst				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza like illness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disease progression				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood glucose increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femoral neck fracture			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheal obstruction			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			

Facial paralysis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysarthria				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depressed level of consciousness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coma				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised tonic-clonic seizure				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocephalus				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic encephalopathy				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage intracranial				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain oedema				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial paresis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Ascites				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric haemorrhage				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Biliary obstruction				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal colic				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue				

disorders				
Arthralgia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bursitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Cellulitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Sepsis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection viral				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hypoalbuminaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypernatraemia				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	0 / 3 (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: 0 %

Non-serious adverse events	Capsule Cohort 2	Capsule Cohort 1	Capsule Cohort 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	5 / 5 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to meninges			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Tumour exudation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Lymphoedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Drug withdrawal syndrome			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	1 / 2 (50.00%)
occurrences (all)	2	1	2
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	2 / 5 (40.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	2
Face oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Penile oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercapnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Disorientation			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Derealisation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Device mechanical issue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Blood uric acid increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Glomerular filtration rate decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Prothrombin time shortened			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine ketone body present			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	4	2	0
Urine analysis abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus test positive			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tibia fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cervical vertebral fracture			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tracheal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural dizziness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cardiovascular disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	2 / 2 (100.00%)	5 / 5 (100.00%)	2 / 2 (100.00%)
occurrences (all)	7	6	5
Dysarthria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	2 / 2 (100.00%)	3 / 5 (60.00%)	1 / 2 (50.00%)
occurrences (all)	13	5	1
Disturbance in attention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hydrocephalus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Mental impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Neuralgia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Radiculitis brachial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 5 (40.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Orthostatic intolerance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Trigeminal nerve disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypoglossal nerve disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
VIth nerve disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hemidysaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cerebrospinal fluid circulation disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Auditory nerve disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Clonal haematopoiesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	8	0	0
Eosinophilia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
External ear pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Keratopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	1	1	0

Abdominal tenderness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	3 / 5 (60.00%)	1 / 2 (50.00%)
occurrences (all)	2	4	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	2 / 5 (40.00%)	2 / 2 (100.00%)
occurrences (all)	0	3	3
Eructation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Discoloured vomit			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pityriasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Rash macular			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Skin burning sensation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sensitive skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Chromaturia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine odour abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	5	0	0
Cystitis noninfective			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Hyperthyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Precocious puberty			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 5 (40.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Lumbar spinal stenosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Osteochondrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sacral pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atypical pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urethritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
H1N1 influenza			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Hyperchloraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	1 / 2 (50.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypernatraemia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Increased appetite			
subjects affected / exposed	0 / 2 (0.00%)	2 / 5 (40.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Metabolic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 5 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 2 (50.00%)	1 / 5 (20.00%)	0 / 2 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Capsule Cohort 4	Capsule Cohort 5a	Capsule Cohort 5b
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	22 / 23 (95.65%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to meninges			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			

subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin papilloma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour exudation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Lymphoedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Haematoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Hot flush			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 8 (12.50%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	1	5	0
Chest discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Chills			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	3	1	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Influenza like illness			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	2 / 8 (25.00%)	5 / 23 (21.74%)	0 / 3 (0.00%)
occurrences (all)	4	6	0
Gait disturbance			
subjects affected / exposed	3 / 8 (37.50%)	6 / 23 (26.09%)	1 / 3 (33.33%)
occurrences (all)	3	9	2
Oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Face oedema			

subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Energy increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 8 (12.50%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	1	5	0
Pain			
subjects affected / exposed	3 / 8 (37.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Pyrexia			
subjects affected / exposed	2 / 8 (25.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	7	4	0
Swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			

subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Scrotal oedema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Scrotal pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Penile oedema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 8 (12.50%)	5 / 23 (21.74%)	0 / 3 (0.00%)
occurrences (all)	1	7	0
Bronchospasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 8 (12.50%)	8 / 23 (34.78%)	0 / 3 (0.00%)
occurrences (all)	1	13	0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercapnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Epistaxis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Respiratory failure			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sneezing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			

subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Anxiety			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Disorientation			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Derealisation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Restlessness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Irritability			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Device mechanical issue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Amylase increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	5 / 23 (21.74%)	1 / 3 (33.33%)
occurrences (all)	0	7	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	4 / 23 (17.39%)	1 / 3 (33.33%)
occurrences (all)	1	8	1
Blood uric acid increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			

subjects affected / exposed	2 / 8 (25.00%)	3 / 23 (13.04%)	1 / 3 (33.33%)
occurrences (all)	2	6	2
Blood bilirubin increased			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Body temperature increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Eosinophil count increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lipase increased			

subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	4 / 8 (50.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	15	12	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Prothrombin time shortened			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Troponin I increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urine ketone body present			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	2 / 8 (25.00%)	5 / 23 (21.74%)	1 / 3 (33.33%)
occurrences (all)	3	10	3
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 8 (12.50%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	1	6	0
Urine analysis abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus test positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	1 / 8 (12.50%)	3 / 23 (13.04%)	1 / 3 (33.33%)
occurrences (all)	1	4	1
Tibia fracture			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cervical vertebral fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tracheal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Radiation skin injury			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural dizziness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cardiovascular disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	7	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	3	2	0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Ataxia			

subjects affected / exposed	4 / 8 (50.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	5	1	0
Dysarthria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	5 / 8 (62.50%)	9 / 23 (39.13%)	2 / 3 (66.67%)
occurrences (all)	8	22	4
Disturbance in attention			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	1 / 3 (33.33%)
occurrences (all)	0	1	4
Depressed level of consciousness			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Burning sensation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	1 / 3 (33.33%)
occurrences (all)	3	3	1
Lethargy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	3
Hydrocephalus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Dyskinesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Mental impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Headache			
subjects affected / exposed	1 / 8 (12.50%)	5 / 23 (21.74%)	1 / 3 (33.33%)
occurrences (all)	2	10	1
Neuropathy peripheral			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Radiculitis brachial			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	2	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Nystagmus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Balance disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Trigeminal nerve disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hypoglossal nerve disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
VIth nerve disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hemidysaesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Cerebrospinal fluid circulation disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Auditory nerve disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Clonal haematopoiesis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	4 / 8 (50.00%)	9 / 23 (39.13%)	0 / 3 (0.00%)
occurrences (all)	12	21	0
Eosinophilia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Tinnitus			

subjects affected / exposed	2 / 8 (25.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
External ear pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Keratopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 8 (12.50%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	1	4	0
Eye disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Visual field defect			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Constipation			
subjects affected / exposed	2 / 8 (25.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	2	4	0
Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	7 / 23 (30.43%)	1 / 3 (33.33%)
occurrences (all)	1	8	2
Abdominal tenderness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Abdominal distension			
subjects affected / exposed	0 / 8 (0.00%)	6 / 23 (26.09%)	1 / 3 (33.33%)
occurrences (all)	0	7	1
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	6 / 8 (75.00%)	8 / 23 (34.78%)	1 / 3 (33.33%)
occurrences (all)	7	11	1
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Salivary hypersecretion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 8 (37.50%)	7 / 23 (30.43%)	1 / 3 (33.33%)
occurrences (all)	3	10	1
Eructation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Anal incontinence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Discoloured vomit			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Toothache			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pityriasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Rash			

subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Photosensitivity reaction			
subjects affected / exposed	2 / 8 (25.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin irritation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1

Skin burning sensation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sensitive skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Chromaturia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nocturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Leukocyturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urinary tract pain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urine odour abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 8 (12.50%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	1	3	0
Precocious puberty			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 8 (25.00%)	4 / 23 (17.39%)	0 / 3 (0.00%)
occurrences (all)	3	5	0
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	5 / 23 (21.74%)	1 / 3 (33.33%)
occurrences (all)	0	7	1
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bursitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Joint stiffness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	2	3	0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	4 / 8 (50.00%)	4 / 23 (17.39%)	1 / 3 (33.33%)
occurrences (all)	11	5	2
Musculoskeletal stiffness			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Osteochondrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Neck mass			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Soft tissue swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Enterovirus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atypical pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonia aspiration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	4	0

Respiratory syncytial virus infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Urethritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	2 / 8 (25.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Skin infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 8 (12.50%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	1	1	0

H1N1 influenza			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Stoma site infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Hyperchloraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	3	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	1 / 3 (33.33%)
occurrences (all)	0	6	2
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			

subjects affected / exposed	0 / 8 (0.00%)	2 / 23 (8.70%)	1 / 3 (33.33%)
occurrences (all)	0	2	2
Hypernatraemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Hyperphosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 8 (12.50%)	2 / 23 (8.70%)	0 / 3 (0.00%)
occurrences (all)	1	6	0
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 8 (12.50%)	4 / 23 (17.39%)	0 / 3 (0.00%)
occurrences (all)	2	4	0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	0 / 3 (0.00%)
occurrences (all)	0	8	0
Hypophosphataemia			
subjects affected / exposed	0 / 8 (0.00%)	3 / 23 (13.04%)	1 / 3 (33.33%)
occurrences (all)	0	3	2
Increased appetite			
subjects affected / exposed	0 / 8 (0.00%)	1 / 23 (4.35%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Metabolic acidosis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 23 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pediatric Cohort 87 mg/mm^2 BID	Suspension Cohort 6b	Suspension Cohort 7b
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to meninges			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour exudation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Lymphoedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematoma			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Gait disturbance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	4
Oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 1 (0.00%)	4 / 4 (100.00%)	2 / 6 (33.33%)
occurrences (all)	0	5	2
Pain			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Pyrexia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Swelling			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Thirst			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile oedema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 1 (0.00%)	4 / 4 (100.00%)	1 / 6 (16.67%)
occurrences (all)	0	4	1
Dyspnoea exertional			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercapnia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pneumothorax			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Respiratory failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sneezing			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Anxiety			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Derealisation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Hallucination			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hallucination, visual			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device loosening			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device mechanical issue			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	8
Alanine aminotransferase increased			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood chloride increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Blood bilirubin increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	2 / 6 (33.33%)
occurrences (all)	0	2	4
Lymphocyte count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	4
Prothrombin time prolonged			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Prothrombin time shortened			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Troponin I increased			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine ketone body present			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	6
Weight increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine analysis abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Respiratory syncytial virus test positive			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			

Hand fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tibia fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cervical vertebral fracture			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Tracheal obstruction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skeletal injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural dizziness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Cardiovascular disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Amnesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 1 (0.00%)	3 / 4 (75.00%)	5 / 6 (83.33%)
occurrences (all)	0	6	9
Disturbance in attention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Autonomic nervous system imbalance			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hydrocephalus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyskinesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Mental impairment			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Myoclonus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neuropathy peripheral			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiculitis brachial			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthostatic intolerance			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Trigeminal nerve disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglossal nerve disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
VIth nerve disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hemidysaesthesia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrospinal fluid circulation disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Auditory nerve disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Clonal haematopoiesis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Eosinophilia			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
External ear pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Keratopathy			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Visual field defect			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Dry mouth			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 1 (100.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Eructation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Paraesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Discoloured vomit			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatomegaly			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pityriasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pain of skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Skin lesion			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin burning sensation			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Scar pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensitive skin			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Urine odour abnormal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Precocious puberty			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	5	1
Back pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bone pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Bursitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Muscular weakness			
subjects affected / exposed	0 / 1 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			

subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteochondrosis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Sacral pain			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Soft tissue swelling			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Limb discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Enterovirus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Atypical pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Pneumonia aspiration			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Urethritis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Rhinitis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
H1N1 influenza			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma site infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperchloraemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Fluid retention			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypermagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Gout			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyperphosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	5
Hypoglycaemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			

subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Decreased appetite			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Increased appetite			
subjects affected / exposed	0 / 1 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	1 / 1 (100.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 1 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Suspension Cohort7a	Pediatric Cohort 58 mg/mm^2 BID	Pediatric Cohort 43 mg/mm^2 BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to meninges			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tumour pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cancer pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour exudation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Lymphoedema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Hypertension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	2
Haematoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Embolism venous			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Flushing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hot flush			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 14 (21.43%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	3	1	2
Gait disturbance			
subjects affected / exposed	3 / 14 (21.43%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Oedema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Face oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Energy increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Peripheral swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Pain			
subjects affected / exposed	3 / 14 (21.43%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Pyrexia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	3 / 6 (50.00%)
occurrences (all)	1	4	6
Swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scrotal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Penile oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 14 (7.14%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	1	5	1
Bronchospasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercapnia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumothorax			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Hypoxia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Haemoptysis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	3
Productive cough			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Respiratory failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Sneezing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lower respiratory tract inflammation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 14 (7.14%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	1	2	3
Wheezing			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2

Delirium			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Disorientation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Derealisation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hallucination, auditory			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	2 / 14 (14.29%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Hallucination, visual			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Irritability			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Product issues			
Device loosening			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Device mechanical issue			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Amylase increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 14 (0.00%)	3 / 4 (75.00%)	1 / 6 (16.67%)
occurrences (all)	0	4	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Blood uric acid increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood chloride increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 14 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	3	0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase			

increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Blood potassium increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood glucose increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 14 (7.14%)	2 / 4 (50.00%)	2 / 6 (33.33%)
occurrences (all)	1	2	7
Prothrombin time prolonged			

subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	2 / 14 (14.29%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	6
Neutrophil count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	9	3
Prothrombin time shortened			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Troponin I increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine ketone body present			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	6	9
Weight increased			
subjects affected / exposed	0 / 14 (0.00%)	3 / 4 (75.00%)	3 / 6 (50.00%)
occurrences (all)	0	6	8
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Urine analysis abnormal			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus test positive			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fibula fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Foot fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	3 / 14 (21.43%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Tibia fracture			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Rib fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cervical vertebral fracture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Tracheal obstruction			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Face injury			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Skeletal injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Procedural dizziness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Procedural headache			

subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Procedural nausea			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Cardiovascular disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Bradycardia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	1
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Amnesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	4 / 14 (28.57%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	9	1	1
Dysarthria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Dizziness			
subjects affected / exposed	8 / 14 (57.14%)	2 / 4 (50.00%)	2 / 6 (33.33%)
occurrences (all)	19	7	4
Disturbance in attention			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	7	0
Depressed level of consciousness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Hypoaesthesia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Memory impairment			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	6	0
Hydrocephalus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dyskinesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	3 / 14 (21.43%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0

Mental impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Nervous system disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 14 (14.29%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	2	2	3
Neuropathy peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Radiculitis brachial			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Presyncope			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nystagmus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Balance disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	3	1
Orthostatic intolerance			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Trigeminal nerve disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cognitive disorder			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	7	0
Hypoglossal nerve disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
VIth nerve disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hemidysaesthesia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cerebrospinal fluid circulation disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Auditory nerve disorder			

subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Clonal haematopoiesis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neutropenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	4 / 14 (28.57%)	2 / 4 (50.00%)	4 / 6 (66.67%)
occurrences (all)	5	2	14
Eosinophilia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Thrombocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
External ear pain			

subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Ear discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Keratopathy			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eye pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Photophobia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	2	1
Vision blurred			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Eye disorder			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Visual field defect			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dyspepsia			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	5 / 14 (35.71%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	6	1	3
Dry mouth			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 14 (14.29%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	2	2	0
Abdominal tenderness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	6 / 14 (42.86%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	7	3	4
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorder			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Faeces discoloured			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Salivary hypersecretion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 14 (35.71%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	5	2	0
Eructation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Discoloured vomit			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

Hepatomegaly			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Pityriasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Rash			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Photosensitivity reaction			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain of skin			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Onycholysis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash macular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin irritation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Skin exfoliation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	3 / 6 (50.00%)
occurrences (all)	1	0	3
Skin burning sensation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Scar pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sensitive skin			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	3
Renal failure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	2 / 14 (14.29%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Urinary tract pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urine odour abnormal			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	3 / 14 (21.43%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Acute kidney injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Precocious puberty			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 14 (14.29%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	3	2	1
Back pain			
subjects affected / exposed	2 / 14 (14.29%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Bone pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Flank pain			

subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Lumbar spinal stenosis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle twitching			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	2 / 14 (14.29%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Myalgia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	4	0	2
Musculoskeletal stiffness			

subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Osteochondrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neck mass			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Soft tissue swelling			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Cellulitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

Atypical pneumonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia aspiration			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Eye infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 14 (0.00%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0

Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 14 (0.00%)	2 / 4 (50.00%)	1 / 6 (16.67%)
occurrences (all)	0	6	1
Urethritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Rhinitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sepsis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	5
H1N1 influenza			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0

COVID-19			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Stoma site infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperchloraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypermagnesaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Hyperkalaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	3	0	1
Hyperglycaemia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Gout			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			

subjects affected / exposed	1 / 14 (7.14%)	3 / 4 (75.00%)	1 / 6 (16.67%)
occurrences (all)	2	3	7
Hyperphosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Hypoalbuminaemia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Hyperuricaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	6
Decreased appetite			
subjects affected / exposed	1 / 14 (7.14%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	2 / 14 (14.29%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	2	1	3
Increased appetite			
subjects affected / exposed	1 / 14 (7.14%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	2
Metabolic acidosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1

Non-serious adverse events	Suspension Cohort 6a		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to meninges			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skin papilloma			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Tumour exudation			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Embolism venous			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Flushing			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Drug withdrawal syndrome			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Fatigue			

subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Gait disturbance				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Oedema				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Malaise				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Face oedema				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Energy increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Peripheral swelling				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Localised oedema				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Oedema peripheral				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pyrexia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Swelling				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Thirst			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Scrotal oedema			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Scrotal pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Penile oedema			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Bronchospasm			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dyspnoea exertional			

subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Hypercapnia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pneumothorax				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Epistaxis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypoxia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Haemoptysis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pleural effusion				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nasal congestion				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Productive cough				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Respiratory failure				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Rhinitis allergic				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Sneezing				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Lower respiratory tract inflammation				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Paranasal sinus discomfort			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Delirium			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Derealisation			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hallucination, auditory			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Depression			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hallucination, visual			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Restlessness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Product issues			
Device loosening			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Device mechanical issue			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	3			
Blood uric acid increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood chloride increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood creatinine increased				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	4			
Blood bilirubin increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood potassium increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood thyroid stimulating hormone increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Glomerular filtration rate decreased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Body temperature increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Electrocardiogram QT prolonged				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Eosinophil count increased				

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Blood glucose increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Oxygen saturation decreased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Lipase increased				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Lymphocyte count decreased				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	7			
Prothrombin time prolonged				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Haemoglobin decreased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Platelet count decreased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Neutrophil count decreased				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Prothrombin time shortened				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Weight decreased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Troponin I increased				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Urine ketone body present				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Blood phosphorus increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	3		
Weight increased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	3		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Urine analysis abnormal			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Breath sounds abnormal			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Respiratory syncytial virus test positive			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Hand fracture			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Fibula fracture			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Foot fracture				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Tibia fracture				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Rib fracture				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	2			
Spinal fracture				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Ligament sprain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Skin laceration				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Cervical vertebral fracture				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Limb injury				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Contusion				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Tracheal obstruction				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Face injury				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skeletal injury			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Radiation skin injury			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Procedural dizziness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Procedural headache			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Procedural nausea			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Cardiovascular disorder			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Ataxia			
subjects affected / exposed	3 / 3 (100.00%)		
occurrences (all)	3		
Dysarthria			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	2 / 3 (66.67%)		
occurrences (all)	3		
Disturbance in attention			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Burning sensation			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Autonomic nervous system imbalance			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Lethargy			

subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Memory impairment				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Hydrocephalus				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dyskinesia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Dysgeusia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Mental impairment				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Myoclonus				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nervous system disorder				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Neuralgia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Headache				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Neuropathy peripheral				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Radiculitis brachial				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Paraesthesia				

subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Peripheral sensory neuropathy				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Presyncope				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nystagmus				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Seizure				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Balance disorder				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Syncope				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Somnolence				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Orthostatic intolerance				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Trigeminal nerve disorder				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Restless legs syndrome				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Cognitive disorder				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	3			
Hypoglossal nerve disorder				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
VIth nerve disorder			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hemidysaesthesia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cerebrospinal fluid circulation disorder			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Auditory nerve disorder			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Clonal haematopoiesis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	4		
Eosinophilia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Thrombocytosis			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
External ear pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Eye disorders			
Keratopathy			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Photophobia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	2		
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Eye disorder			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Diplopia			

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Visual field defect			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Dry mouth			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Abdominal tenderness			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		

Dysphagia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nausea				
subjects affected / exposed	2 / 3 (66.67%)			
occurrences (all)	3			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Gastrointestinal disorder				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Faeces discoloured				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Salivary hypersecretion				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Vomiting				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	2			
Eructation				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Paraesthesia oral				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Anal incontinence				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

Discoloured vomit subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hypoaesthesia oral subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Stomatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Toothache subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Hepatobiliary disorders Hepatomegaly subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Skin and subcutaneous tissue disorders Dermatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Erythema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Eczema subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Dry skin subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Pityriasis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hyperhidrosis			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Night sweats				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Rash				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Photosensitivity reaction				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Palmar-plantar erythrodysaesthesia syndrome				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pain of skin				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Onycholysis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Rash macular				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Seborrhoeic dermatitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Skin lesion				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Skin irritation				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

Skin exfoliation				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Urticaria				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Skin burning sensation				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Scar pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Sensitive skin				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Renal and urinary disorders				
Dysuria				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Chromaturia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Proteinuria				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pollakiuria				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nocturia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Renal failure				

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Leukocyturia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Urinary retention subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Urinary tract pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Urine odour abnormal subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Acute kidney injury subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Cystitis noninfective subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Endocrine disorders			
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Precocious puberty subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

Arthralgia				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Back pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Bone pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Bursitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Flank pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Groin pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Joint stiffness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Muscular weakness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Lumbar spinal stenosis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Joint swelling				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	2			
Muscle twitching				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Muscle spasms				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

Musculoskeletal pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Osteoarthritis				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Neck pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Musculoskeletal stiffness				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Osteochondrosis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Neck mass				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Sacral pain				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Pain in extremity				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Soft tissue swelling				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Limb discomfort				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			

Musculoskeletal discomfort			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Enterovirus infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Atypical pneumonia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Cellulitis staphylococcal			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Pneumonia aspiration			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Eye infection			

subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Oral candidiasis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hordeolum				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Urinary tract infection				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Urethritis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Skin infection				

subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
H1N1 influenza			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Stoma site infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Mucosal infection			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hyperchloraemia			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)		
occurrences (all)	0		
Hypermagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)		
occurrences (all)	1		

Hyperkalaemia				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Hyperglycaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Gout				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypercalcaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypernatraemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hyperphosphataemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	1			
Hypoalbuminaemia				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	3			
Hyperuricaemia				
subjects affected / exposed	1 / 3 (33.33%)			
occurrences (all)	2			
Hypoglycaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Hypokalaemia				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			
Decreased appetite				
subjects affected / exposed	0 / 3 (0.00%)			
occurrences (all)	0			

Hyponatraemia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1		
Hypophosphataemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Increased appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Metabolic acidosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 May 2017	Updated objectives and endpoints Clarified DLT definitions Modified inclusion/exclusion criteria Clarified reconsent procedure Clarified tumor assessment procedure
22 May 2017	Updated study design to include patients aged 12 and older Added new cohort and updated sample size Updated objectives and endpoints Updated dose levels Updated SRC meeting frequency Modified inclusion/exclusion criteria
18 October 2017	Updated study design to include patients at least 1 month of age Updated objectives and endpoints, analyses, and sample size Updated dose reduction guidelines Modified DLT criteria Clarified schedules, dosing and dose escalation rules, and MTD determination Updated SRC guidance Updated serious adverse event (SAE) reporting Modified Inclusion Criteria Updated study drug formulation and dosing instructions Modified PK assessments Updated clinical results
17 May 2018	Updated endpoints Updated intra-patient dose escalation and re-escalation guidelines Modified DLT criteria and guidance Updated guidance for safety monitoring Modified inclusion/exclusion criteria Updated dosing instructions and guidelines Updated information on end of study Modified PK assessments Updated guidance on blood sample and tumor biopsy collection and laboratory assessments
17 September 2018	Added new cohort added and updated sample size Updated dose and schedule, dose escalation and maximum dose cleared for safety Clarified DLT assessment and dose escalation guidelines Clarified enrollment procedure
15 October 2019	Added new cohort and updated sample size Updated endpoints Updated safety measures Modified inclusion/exclusion criteria Modified PK sampling timepoints and time windows
21 January 2020	Included neurological assessment as part of the physical exam Clarified instructions for request for neurological consult
25 August 2020	Updated dose escalation design Updated patient numbers for dose escalation and expansion Added taste and texture questionnaire Updated guidance on blood sample collection Modified inclusion/exclusion criteria
21 April 2022	Changed study design due to Sponsor’s decision to discontinue selitrectinib development activities, close the study enrollment of Phase 1 and not conduct the Phase 2 part of the study Updated planned analyses Updated visit schedule

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported