Clinical trial results:
A Phase I/II, multicenter, open-label study of oral FGF401 in adult patients with hepatocellular carcinoma or solid malignancies characterized by positive FGFR4 and KLB expression

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Summary

EudraCT number	2014-002929-35
Trial protocol	ES DE FR
Global end of trial date	30 May 2019
Results information	
Result version number	v1 (current)
This version publication date	14 June 2020
First version publication date	14 June 2020

Trial information

Trial identification	
Sponsor protocol code	CFGF401X2101
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02325739
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Novartis Pharma, AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma, AG, 41 613241111, novartis.email@novartis.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	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 May 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase I part: To estimate the maximum tolerated dose (MTD) and/or recommended Phase II dose (RP2D) of FGF401 single agent and in combination with PDR001.

Phase II part: To investigate the anti-tumor activity of FGF401 single agent and in combination with PDR001.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 46
Country: Number of subjects enrolled	China: 1
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Hong Kong: 22
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Japan: 11
Country: Number of subjects enrolled	Korea, Republic of: 19
Country: Number of subjects enrolled	Singapore: 9
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Taiwan: 19
Country: Number of subjects enrolled	United States: 7
Worldwide total number of subjects	172
EEA total number of subjects	84

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	96
From 65 to 84 years	75
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

160 subjects were enrolled & treated with FGF401 single agent. In the Phase I part 74 subjects & 86 subjects in the Phase II part. 12 subjects were treated in the Phase I of the combination of FGF401 and PDR001. All subjects completed the study as per protocol & reasons for discontinuation of treatment are provided in the 'Not Completed' section.

Pre-assignment

Screening details:

At least 21 evaluable subjects were to be treated in Phase I for the model to have reasonable operating characteristics relating to its MTD &/or RP2D. Each group in the Phase II dose expansion targeted a different number of subjects. Group 1 & Group 2 planned to enroll around 40 subjects each & Group 3 planned to enroll approximately 20 subjects.

Period 1

Period 1 title	Phase I and Phase II (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	Phase I: 50 mg Fasted

Arm description:

Participants received 50 mg of FGF401 while fasted

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase I: 80 mg Fasted

Arm description:

Participants received 80 mg of FGF401 while fasted

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase I: 80 mg Fed

Arm description:

Participants received 80 mg of FGF401 while fed.

Arm type	Experimental

Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase I: 120 mg Fasted

Arm description:

Participants received 120 mg of FGF401 while fasted

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase I: 120 mg Fed

Arm description:

Participants received 120 mg of FGF401 while fed.

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase I: 150 mg Fasted

Arm description:

Participants received 150 mg of FGF401 while fasted.

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase I: FGF401 80 mg + PDR001 300 mg

Arm description:

Participants received 80 mg of FGF401 and 300 mg of PDR001 while fasted.

Arm type	Experimental

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 was taken every three weeks (3QW)

Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase I: FGF401 120 mg + PDR001 300 mg

Arm description:

Participants received 120 mg of FGF401 and 300mg of PDR001 while fasted

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Investigational medicinal product name	PDR001
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

PDR001 was taken every three weeks (3QW)

Arm title	Phase II: Group 1

Arm description:

Group 1 comprised of HCC participants from Asian countries

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase II: Group 2

Arm description:

HCC subjects from non-Asian countries

Arm type	Experimental

Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Arm title	Phase II: Group 3

Arm description:

Subjects with other solid malignancies regardless of geography

Arm type	Experimental
Investigational medicinal product name	FGF401
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

FGF401 was taken on a flat scale of mg/day once daily (QD) on a continuous dosing regimen or the combination of FGF401 on a continuous once daily dosing regimen.

Number of subjects in period 1	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed
Started	11	6	5
Completed	0	0	0
Not completed	11	6	5
Adverse event, serious fatal	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	1	-	1
Progressive disease	9	6	3
Subject/guardian decision	1	-	1

Number of subjects in period 1	Phase I: 120 mg Fasted	Phase I: 120 mg Fed	Phase I: 150 mg Fasted
Started	26	19	7
Completed	0	0	0
Not completed	26	19	7
Adverse event, serious fatal	-	2	-
Physician decision	-	-	-
Adverse event, non-fatal	2	3	1
Progressive disease	23	14	6
Subject/guardian decision	1	-	-

Number of subjects in period 1	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg	Phase II: Group 1
Started	6	6	30

Completed	0	0	0
Not completed	6	6	30
Adverse event, serious fatal	-	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	2	4
Progressive disease	6	3	22
Subject/guardian decision	-	1	4

Number of subjects in period 1	Phase II: Group 2	Phase II: Group 3
Started	36	20
Completed	0	0
Not completed	36	20
Adverse event, serious fatal	-	-
Physician decision	1	-
Adverse event, non-fatal	5	1
Progressive disease	29	18
Subject/guardian decision	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Phase I: 50 mg Fasted
Reporting group description: Participants received 50 mg of FGF401 while fasted	
Reporting group title	Phase I: 80 mg Fasted
Reporting group description: Participants received 80 mg of FGF401 while fasted	
Reporting group title	Phase I: 80 mg Fed
Reporting group description: Participants received 80 mg of FGF401 while fed.	
Reporting group title	Phase I: 120 mg Fasted
Reporting group description: Participants received 120 mg of FGF401 while fasted	
Reporting group title	Phase I: 120 mg Fed
Reporting group description: Participants received 120 mg of FGF401 while fed.	
Reporting group title	Phase I: 150 mg Fasted
Reporting group description: Participants received 150 mg of FGF401 while fasted.	
Reporting group title	Phase I: FGF401 80 mg + PDR001 300 mg
Reporting group description: Participants received 80 mg of FGF401 and 300 mg of PDR001 while fasted.	
Reporting group title	Phase I: FGF401 120 mg + PDR001 300 mg
Reporting group description: Participants received 120 mg of FGF401 and 300mg of PDR001 while fasted	
Reporting group title	Phase II: Group 1
Reporting group description: Group 1 comprised of HCC participants from Asian countries	
Reporting group title	Phase II: Group 2
Reporting group description: HCC subjects from non-Asian countries	
Reporting group title	Phase II: Group 3
Reporting group description: Subjects with other solid malignancies regardless of geography	

Reporting group values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed
Number of subjects	11	6	5
Age Categorical Units: participants			
18 y - <65 y	6	4	3
65 y - <85 y	5	2	2
>=85 y	0	0	0
Sex: Female, Male Units: participants			
Female	4	1	1
Male	7	5	4

Race/Ethnicity, Customized Units: Subjects			
Asian	9	2	2
Black	0	0	0
Caucasian	2	4	3
Not applicable	0	0	0
Other	0	0	0
Pacific Islander	0	0	0
Unknown	0	0	0

Reporting group values	Phase I: 120 mg Fasted	Phase I: 120 mg Fed	Phase I: 150 mg Fasted
Number of subjects	26	19	7
Age Categorical Units: participants			
18 y - <65 y	14	12	4
65 y - <85 y	12	6	3
>=85 y	0	1	0
Sex: Female, Male Units: participants			
Female	3	6	0
Male	23	13	7
Race/Ethnicity, Customized Units: Subjects			
Asian	14	10	4
Black	0	1	1
Caucasian	12	8	1
Not applicable	0	0	0
Other	0	0	0
Pacific Islander	0	0	0
Unknown	0	0	1

Reporting group values	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg	Phase II: Group 1
Number of subjects	6	6	30
Age Categorical Units: participants			
18 y - <65 y	3	3	22
65 y - <85 y	3	3	8
>=85 y	0	0	0
Sex: Female, Male Units: participants			
Female	1	4	8
Male	5	2	22
Race/Ethnicity, Customized Units: Subjects			
Asian	3	5	30
Black	0	0	0
Caucasian	3	1	0
Not applicable	0	0	0
Other	0	0	0
Pacific Islander	0	0	0

Unknown	0	0	0

Reporting group values	Phase II: Group 2	Phase II: Group 3	Total
Number of subjects	36	20	172
Age Categorical Units: participants			
18 y - <65 y	15	10	96
65 y - <85 y	21	10	75
>=85 y	0	0	1
Sex: Female, Male Units: participants			
Female	7	12	47
Male	29	8	125
Race/Ethnicity, Customized Units: Subjects			
Asian	0	2	81
Black	0	0	2
Caucasian	21	11	66
Not applicable	1	0	1
Other	1	0	1
Pacific Islander	1	0	1
Unknown	12	7	20

End points

End points reporting groups

Reporting group title	Phase I: 50 mg Fasted
Reporting group description: Participants received 50 mg of FGF401 while fasted	
Reporting group title	Phase I: 80 mg Fasted
Reporting group description: Participants received 80 mg of FGF401 while fasted	
Reporting group title	Phase I: 80 mg Fed
Reporting group description: Participants received 80 mg of FGF401 while fed.	
Reporting group title	Phase I: 120 mg Fasted
Reporting group description: Participants received 120 mg of FGF401 while fasted	
Reporting group title	Phase I: 120 mg Fed
Reporting group description: Participants received 120 mg of FGF401 while fed.	
Reporting group title	Phase I: 150 mg Fasted
Reporting group description: Participants received 150 mg of FGF401 while fasted.	
Reporting group title	Phase I: FGF401 80 mg + PDR001 300 mg
Reporting group description: Participants received 80 mg of FGF401 and 300 mg of PDR001 while fasted.	
Reporting group title	Phase I: FGF401 120 mg + PDR001 300 mg
Reporting group description: Participants received 120 mg of FGF401 and 300mg of PDR001 while fasted	
Reporting group title	Phase II: Group 1
Reporting group description: Group 1 comprised of HCC participants from Asian countries	
Reporting group title	Phase II: Group 2
Reporting group description: HCC subjects from non-Asian countries	
Reporting group title	Phase II: Group 3
Reporting group description: Subjects with other solid malignancies regardless of geography	

Primary: Incidence rate of Dose-limiting Toxicity (DLT): Phase I only

End point title	Incidence rate of Dose-limiting Toxicity (DLT): Phase I only[1][2]

End point description:

A dose-limiting toxicity was defined as an adverse event or abnormal laboratory value assessed as unrelated to disease, disease progression, inter-current illness, or concomitant medications that occurred within the evaluation period of DLTs and met any of the criteria listed. The estimation of the maximum tolerated dose (MTD)/recommended phase 2 dose (RP2D) of the treatment was based upon the estimation of the probability of DLT during the evaluation period for subjects in the dose determining set (DDS). A subject with multiple occurrences of a DLT under one treatment is counted only once in the AE category for that treatment. A subject with multiple DLTs within a primary system organ class is counted only once in the total row.

End point type	Primary

End point timeframe:

Cycle 1 (C1) (21 days) for FGF401 single agent, Cycle 1 and Cycle 2 (C2) (42 days) for FGF401 and PDR001 combination

Notes:

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

[2] - 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: No statistical analysis was planned for this endpoint

End point values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed	Phase I: 120 mg Fasted
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	6	5	23
Units: Percentage of DLTs				
number (not applicable)				
Any Primary system organ class (SOC)	10.0	0	0	4.3
Invest.: Aspartate Aminotrans. increased	0	0	0	4.3
Invest.: Alanine aminotrans. increased	10.0	0	0	0
Invest.: Blood bilirubin increased	0	0	0	0

End point values	Phase I: 120 mg Fed	Phase I: 150 mg Fasted	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	7	6	6
Units: Percentage of DLTs				
number (not applicable)				
Any Primary system organ class (SOC)	5.6	42.9	0	0
Invest.: Aspartate Aminotrans. increased	0	42.9	0	0
Invest.: Alanine aminotrans. increased	0	14.3	0	0
Invest.: Blood bilirubin increased	5.6	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Time to progression (TTP): Group 1 & Group 2 (Phase II only)

End point title	Time to progression (TTP): Group 1 & Group 2 (Phase II

End point description:

TTP is defined as the date of start treatment to the date of event defined as the first documented progression or death due to underlying cancer. Method used was Kaplan-Meier analysis.
Group 1: HCC subjects form Asian countries
Group 2: HCC subjects form non-Asian countries

End point type	Primary

End point timeframe:

5 years

Notes:

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

[4] - 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: No statistical analysis was planned for this endpoint

End point values	Phase II: Group 1	Phase II: Group 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	36		
Units: months				
median (confidence interval 90%)	2.6 (1.3 to 999)	3.9 (2.9 to 999)		

Statistical analyses

No statistical analyses for this end point

Primary: Overall response rate (ORR) based on local assessment: Group 3 (Phase II only)

End point title	Overall response rate (ORR) based on local assessment: Group 3 (Phase II only)[5][6]

End point description:

ORR is defined as the percentage of patients with a best overall response of CR or PR (RECIST v1.1). FGF401 single agent-Phase II part - Group 3 (non-HCC, other solid tumors).

End point type	Primary

End point timeframe:

5 years

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analysis was planned for this endpoint

[6] - 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: No statistical analysis was planned for this endpoint

End point values	Phase II: Group 3			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 16.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR) by Investigator assessment: Phase I and Phase II

End point title	Best Overall Response (BOR) by Investigator assessment: Phase I and Phase II

End point description:

BOR is the best response recorded from the start of the treatment until disease progression/recurrence. BOR is determined according to: complete response (CR), partial response (PR), stable disease (SD), progressive disease (PD) and unknown.

End point type	Secondary

End point timeframe:

5 years

End point values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed	Phase I: 120 mg Fasted
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	6	5	26
Units: participants				
Complete Response	0	0	0	1
Partial Response	0	1	1	0
Stable Disease	2	1	2	12
Progressive Disease	7	4	1	11
Unknown	2	0	1	2

End point values	Phase I: 120 mg Fed	Phase I: 150 mg Fasted	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	7	6	6
Units: participants				
Complete Response	0	0	0	0
Partial Response	0	1	1	1
Stable Disease	9	4	2	2
Progressive Disease	8	2	3	1
Unknown	2	0	0	2

End point values	Phase II: Group 1	Phase II: Group 2	Phase II: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	36	20	
Units: participants				
Complete Response	0	0	0	
Partial Response	2	2	0	
Stable Disease	11	20	6	

Progressive Disease	16	6	12	
Unknown	1	8	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Response Rate (ORR) by Investigator assessment Phase I and FGF401 single agent Phase II Groups 1 & 2

End point title	Overall Response Rate (ORR) by Investigator assessment Phase I and FGF401 single agent Phase II Groups 1 & 2

End point description:

ORR is defined as the proportion of patients with a best overall response of CR or PR (RECIST v1.1). Phase I part and FGF401 single agent Phase II Group 1 (HCC, Asians) and Group 2 (HCC, non-Asians)

End point type	Secondary

End point timeframe:

5 years

End point values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed	Phase I: 120 mg Fasted
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	6	5	26
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 28.5)	16.7 (0.4 to 64.1)	20.0 (0.5 to 71.6)	3.8 (0.1 to 19.6)

End point values	Phase I: 120 mg Fed	Phase I: 150 mg Fasted	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	7	6	6
Units: Percentage of participants				
number (confidence interval 95%)	0 (0.0 to 17.6)	14.3 (0.4 to 57.9)	16.7 (0.4 to 64.1)	16.7 (0.4 to 64.1)

End point values	Phase II: Group 1	Phase II: Group 2	Phase II: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	36	0[7]	
Units: Percentage of participants				
number (confidence interval 95%)	6.7 (0.8 to 22.1)	5.6 (0.7 to 18.7)	(to)	

Notes:

[7] - This arm was not analyzed for this endpoint.

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR) by local Investigator assessment Phase I and FGF401 single agent Phase II Groups 1, 2 & 3

End point title	Disease Control Rate (DCR) by local Investigator assessment Phase I and FGF401 single agent Phase II Groups 1, 2 & 3

End point description:

DCR is the percentage of participants with a best overall response of CR or PR or SD per local assessment according to RECIST v1.1. Phase I part and FGF401 single agent Phase II Group 1 (HCC, Asians) and Group 2 (HCC, non-Asians) and Group 3 (non-HCC, other solid tumors).

End point type	Secondary

End point timeframe:

5 years

End point values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed	Phase I: 120 mg Fasted
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	6	5	26
Units: percentage of participants				
number (confidence interval 95%)	18.2 (2.3 to 51.8)	33.3 (4.3 to 77.7)	60.0 (14.7 to 94.7)	50.0 (29.9 to 70.1)

End point values	Phase I: 120 mg Fed	Phase I: 150 mg Fasted	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	7	6	6
Units: percentage of participants				
number (confidence interval 95%)	47.4 (24.4 to 71.1)	71.4 (29.0 to 96.3)	50.0 (11.8 to 88.2)	50.0 (11.8 to 88.2)

End point values	Phase II: Group 1	Phase II: Group 2	Phase II: Group 3	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	30	36	20	
Units: percentage of participants				
number (confidence interval 95%)	43.3 (25.5 to 62.6)	61.1 (43.5 to 76.9)	30.0 (11.9 to 54.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Progression (TTP) - Phase I (single agent FGF401 & in combination with PDR001) dosed at RP2D

End point title	Time to Progression (TTP) - Phase I (single agent FGF401 & in combination with PDR001) dosed at RP2D[8]

End point description:

TTP is defined as the date of start treatment to the date of event defined as the first documented progression or death due to underlying cancer. Method used was Kaplan-Meier analysis.

End point type	Secondary

End point timeframe:

5 years

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: No statistical analysis was planned for this endpoint

End point values	Phase I: 120 mg Fasted	Phase I: 120 mg Fed	Phase I: FGF401 120 mg + PDR001 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	26	19	6	
Units: months				
median (confidence interval 90%)	4.1 (1.6 to 999)	2.0 (1.4 to 999)	5.3 (3.0 to 999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) - Phase I (single agent & combination) dosed at RP2D and Phase II FGF401 single agent

End point title	Overall Survival (OS) - Phase I (single agent & combination) dosed at RP2D and Phase II FGF401 single agent[9]

End point description:

Overall survival (OS) is defined as the time from date of start of treatment to date of death due to any cause. If a patient was not known to have died, survival was censored at the date of last known date patient alive. Method used was Kaplan-Meier analysis.

End point type	Secondary

End point timeframe:

start of treatment to death, up to about 53 months

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: No statistical analysis was planned for this endpoint

End point values	Phase I: 120 mg Fasted	Phase I: 120 mg Fed	Phase I: FGF401 120 mg + PDR001 300 mg	Phase II: Group 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	19	6	30
Units: months				
median (confidence interval 90%)	7.0 (5.1 to 999)	4.9 (2.6 to 999)	999 (999 to 999)	5.9 (5.1 to 999)

End point values	Phase II: Group 2	Phase II: Group 3		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	20		
Units: months				
median (confidence interval 90%)	10.9 (7.9 to 999)	6.2 (4.2 to 999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free Survival (PFS) - FGF401 single agent Phase II: Group 3

End point title	Progression-free Survival (PFS) - FGF401 single agent Phase II: Group 3[10]

End point description:

Progression-free survival (PFS) is the time from date of start of treatment to the date of event defined as the first documented progression or death due to any cause. If a patient has not had an event, progression-free survival is censored at the date of last adequate tumor assessment. Group 3 - non-HCC, other solid tumors. Method used was Kaplan-Meier analysis.

End point type	Secondary

End point timeframe:

5 years

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for this endpoint

End point values	Phase II: Group 3			
Subject group type	Reporting group			
Number of subjects analysed	20			
Units: months				
median (confidence interval 95%)	1.4 (1.4 to 2.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Presence and/or concentration of anti-PDR001 antibodies

End point title	Presence and/or concentration of anti-PDR001 antibodies[11]

End point description:

Serum PDR001 concentrations as well as immunogenicity analysis were performed for all subjects receiving PDR001. Treatment-induced ADA-positive percentage was based on percentage subjects ADA-negative at baseline. Treatment-boosted ADA-positive percentage was based on subjects ADA-positive at baseline.

End point type	Secondary

End point timeframe:

Day 1 of Cycle 1 to 6, approx. 10 months after C1D1 and 150-day safety ollow up (FU)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for this endpoint

End point values	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: percentage of participants				
number (not applicable)				
ADA-negative	100.0	83.3		
ADA-positive (i.e. ADA incidence)	0	16.7		
Treatment-induced ADA-positive	0	20.0		
Treatment-boosted ADA-positive	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of PDR001 in combination with FGF401: Phase I

End point title	Cmax of PDR001 in combination with FGF401: Phase I[12]

End point description:

Cmax is the maximum (peak) observed plasma drug concentration (mass x volume-1)

End point type	Secondary

End point timeframe:

After the first dosing sample collection was at: C1D1 0hr , C1D1 1hr, C1D8 168hr, C1D15 336hr, C2D1 504hr; each cycle is 21 days

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: No statistical analysis was planned for this endpoint

End point values	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: µg/mL				
geometric mean (geometric coefficient of variation)	74.7 (± 43.0)	87.7 (± 5.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUClast and AUCtau of PDR001 in combination with FGF401: Phase I

End point title	AUClast and AUCtau of PDR001 in combination with FGF401: Phase I[13]

End point description:

AUClast: The AUC from time zero to the last measurable concentration sampling time (tlast) (mass x time x volume-1)

AUCtau: The AUC calculated to the end of a dosing interval (tau) (amount x time x volume-1)

End point type	Secondary

End point timeframe:

After the first dosing sample collection was at: C1D1 0hr , C1D1 1hr, C1D8 168hr, C1D15 336hr, C2D1 504hr; each cycle is 21 days

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: No statistical analysis was planned for this endpoint

End point values	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: day*µg/mL				
geometric mean (geometric coefficient of variation)				
AUClast	795 (± 34.5)	978 (± 15.8)		
AUC0-504h (n = 3, 6)	760 (± 1.9)	967 (± 13.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: T1/2 of PDR001: Phase I

End point title	T1/2 of PDR001: Phase I[14]

End point description:

Due to the sparse PK sampling designed from PDR001, the PDR001 concentration data was insufficient for accurate estimation of secondary PK parameters including T1/2 which were considered not reportable

End point type	Secondary

End point timeframe:

After the first dosing sample collection was at: C1D1 0hr , C1D1 1hr, C1D8 168hr, C1D15 336hr, C2D1 504hr; each cycle is 21 days

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: No statistical analysis was planned for this endpoint

End point values	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[15]	0[16]		
Units: hour (hr)				
arithmetic mean (standard deviation)	()	()		

Notes:

[15] - This endpoint was not analyzed

[16] - This endpoint was not analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of FGF401: Phase I

End point title	Cmax of FGF401: Phase I[17]

End point description:

Cmax is the maximum (peak) observed plasma drug concentration (mass x volume-1)

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 & Day 8, Cycle 2 Day 1 (each cycle is 21 days)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for this endpoint

End point values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed	Phase I: 120 mg Fasted
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	6	5	26
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=6, 5, 5, 26, 19,7)	698 (± 36.1)	967 (± 25.0)	659 (± 15.2)	1090 (± 37.9)

Cycle 1 Day 8 (7, 6, 4, 24, 18, 6)	663 (± 46.8)	838 (± 16.5)	704 (± 22.1)	1120 (± 36.5)
Cycle 2 Day 1 (n = 9, 6, 5, 22, 17, 4)	696 (± 44.2)	786 (± 25.5)	703 (± 41.7)	1070 (± 32.2)

End point values	Phase I: 120 mg Fed	Phase I: 150 mg Fasted		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	7		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1 (n=6, 5, 5, 26, 19,7)	1050 (± 32.3)	1400 (± 32.1)		
Cycle 1 Day 8 (7, 6, 4, 24, 18, 6)	1060 (± 22.1)	1070 (± 46.0)		
Cycle 2 Day 1 (n = 9, 6, 5, 22, 17, 4)	1000 (± 23.9)	1350 (± 28.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of FGF401 in combination with PDR001: Phase I

End point title	Cmax of FGF401 in combination with PDR001: Phase I[18]

End point description:

Cmax is the maximum (peak) observed plasma drug concentration (mass x volume-1)

End point type	Secondary

End point timeframe:

Cycle 1 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: No statistical analysis was planned for this endpoint

End point values	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	732 (± 26.8)	1450 (± 31.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf, AUClast & AUCtau of FGF401: Phase I

End point title	AUCinf, AUClast & AUCtau of FGF401: Phase I[19]

End point description:

AUCinf: The AUC from time zero to infinity (mass x time x volume-1)

AUClast: The AUC from time zero to the last measurable concentration sampling time (tlast) (mass x time x volume-1)

AUCtau: The AUC calculated to the end of a dosing interval (tau) (amount x time x volume-1)

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 & Day 8, Cycle 2 Day 1 (each cycle is 21 days)

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: No statistical analysis was planned for this endpoint

End point values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed	Phase I: 120 mg Fasted
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	6	5	26
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
AUCinf C1D1 (n = 6, 5, 4, 24, 17,7)	4920 (± 51.9)	5090 (± 32.9)	5560 (± 23.1)	7210 (± 35.4)
AUClast C1D1 (n =6, 5, 5, 26, 19, 7)	4610 (± 50.4)	4710 (± 38.0)	4600 (± 39.2)	6710 (± 35.6)
AUCtau C1D1 (n = 6, 5, 5, 26, 18, 7)	4610 (± 50.4)	4910 (± 30.3)	4860 (± 29.4)	6840 (± 33.6)
AUCinf C1D8 (n = 6, 6, 4, 18, 15, 6)	3650 (± 71.9)	5130 (± 28.9)	5550 (± 23.2)	7590 (± 43.0)
AUClast C1D8 (n = 6, 6, 4, 24, 18, 6)	3460 (± 62.5)	4840 (± 27.0)	5280 (± 23.9)	6480 (± 47.5)
AUCtau C1D8 (n = 7, 6, 4, 24, 16, 6)	3650 (± 65.6)	4850 (± 27.0)	5290 (± 24.0)	6970 (± 38.7)
AUCinf C2D1 (n = 9, 6, 5, 22, 13, 4)	4390 (± 54.0)	4580 (± 30.6)	5110 (± 44.3)	7770 (± 33.2)
AUClast C2D1 (n = 9, 6, 5, 22, 17, 4)	4100 (± 52.9)	4210 (± 32.5)	4880 (± 43.1)	7260 (± 33.6)
AUCtau C2D1 (n = 9, 6, 5, 22, 15, 4)	4100 (± 52.7)	4360 (± 28.5)	4870 (± 43.7)	7330 (± 31.7)

End point values	Phase I: 120 mg Fed	Phase I: 150 mg Fasted		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	7		
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
AUCinf C1D1 (n = 6, 5, 4, 24, 17,7)	8520 (± 35.2)	8190 (± 42.7)		
AUClast C1D1 (n =6, 5, 5, 26, 19, 7)	7850 (± 34.1)	7920 (± 42.0)		
AUCtau C1D1 (n = 6, 5, 5, 26, 18, 7)	8020 (± 33.5)	7930 (± 41.8)		
AUCinf C1D8 (n = 6, 6, 4, 18, 15, 6)	7980 (± 25.1)	7850 (± 29.4)		
AUClast C1D8 (n = 6, 6, 4, 24, 18, 6)	7640 (± 33.1)	7550 (± 28.6)		
AUCtau C1D8 (n = 7, 6, 4, 24, 16, 6)	7330 (± 26.7)	7510 (± 29.8)		
AUCinf C2D1 (n = 9, 6, 5, 22, 13, 4)	8760 (± 23.5)	7850 (± 25.7)		
AUClast C2D1 (n = 9, 6, 5, 22, 17, 4)	7520 (± 38.7)	7610 (± 25.8)		
AUCtau C2D1 (n = 9, 6, 5, 22, 15, 4)	7830 (± 23.4)	7620 (± 25.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUCinf, AUClast & AUCtau of FGF401 in combination with PDR001: Phase I

End point title	AUCinf, AUClast & AUCtau of FGF401 in combination with PDR001: Phase I[20]

End point description:

AUCinf: The AUC from time zero to infinity (mass x time x volume-1)

AUClast: The AUC from time zero to the last measurable concentration sampling time (tlast) (mass x time x volume-1)

AUCtau: The AUC calculated to the end of a dosing interval (tau) (amount x time x volume-1)

End point type	Secondary

End point timeframe:

Cycle 1 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: No statistical analysis was planned for this endpoint

End point values	Phase I: FGF401 80 mg + PDR001 300 mg	Phase I: FGF401 120 mg + PDR001 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
AUCinf	5030 (± 25.5)	7540 (± 37.0)		
AUClast	4760 (± 25.0)	7280 (± 36.7)		
AUCtau	4770 (± 24.4)	7280 (± 36.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: T1/2 of FGF401: Phase I

End point title	T1/2 of FGF401: Phase I[21]

End point description:

The elimination half-life associated with the terminal slope (z) of a semi logarithmic concentration-time curve (time).

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 & Day 8, Cycle 2 Day 1 (each cycle is 21 days)

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis was planned for this endpoint

End point values	Phase I: 50 mg Fasted	Phase I: 80 mg Fasted	Phase I: 80 mg Fed	Phase I: 120 mg Fasted
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	6	5	26
Units: hour (hr)				
geometric mean (geometric coefficient of variation)				
C1D1 (n = 6, 5, 4, 24, 17, 7)	6.27 (± 16.2)	4.91 (± 31.6)	5.2 (± 8.8)	5.47 (± 14.4)
C1D8 (n = 6, 6, 4, 18, 15, 6)	6.57 (± 16.6)	6.08 (± 13.8)	5.58 (± 12.0)	5.43 (± 30.0)
C2D1 (n = 9, 6, 5, 22, 13, 4)	6.46 (± 18.9)	5.44 (± 34.9)	5.43 (± 17.2)	5.8 (± 22.1)

End point values	Phase I: 120 mg Fed	Phase I: 150 mg Fasted		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	7		
Units: hour (hr)				
geometric mean (geometric coefficient of variation)				
C1D1 (n = 6, 5, 4, 24, 17, 7)	5.16 (± 16.3)	5 (± 11.3)		
C1D8 (n = 6, 6, 4, 18, 15, 6)	5.58 (± 17.1)	5.24 (± 12.4)		
C2D1 (n = 9, 6, 5, 22, 13, 4)	5.81 (± 20.2)	4.92 (± 14.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

.Adverse Events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All Adverse events are reported in this
record from First Patient First Treatment until Last Patient Last Visit.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from
adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Phase I Part 50 mg Fasted

Reporting group description:

Participants received 50 mg of FGF401 while fasted

Reporting group title	Phase I Part 80 mg Fasted

Reporting group description:

Participants received 80 mg of FGF401 while fasted

Reporting group title	Phase I Part 80 mg Fed

Reporting group description:

Participants received 80 mg of FGF401 while fed

Reporting group title	Phase I Part 120 mg Fasted

Reporting group description:

Participants received 120 mg of FGF401 while fasted

Reporting group title	Phase I Part 120 mg Fed

Reporting group description:

Participants received 120 mg of FGF401 while fed

Reporting group title	Phase I Part 150 mg Fasted

Reporting group description:

Participants received 150 mg of FGF401 while fasted

Reporting group title	Phase II Part Group 1

Reporting group description:

This group is comprised of HCC participants from Asian countries who received the RP2D of FGF401 while fasted

Reporting group title	Phase II Part Group 2

Reporting group description:

This group is comprised of HCC participants from non- Asian countries who received the RP2D of FGF401 while fasted

Reporting group title	Phase II Part Group 3

Reporting group description:

This group comprised of participants with other solid malignancies regardless of geography who received the RP2D of FGF401 while fasted

Reporting group title	All Patients Single agent

Reporting group description:

This group comprised of all participants who took single agent FGF401

Reporting group title	Phase I Part FGF401 80 mg + PDR001 300 mg

Reporting group description:

Participants received 80 mg of FGF401 and 300 mg of PDR001 while fasted.

Reporting group title	Phase I Part FGF401 120 mg + PDR001 300 mg

Reporting group description:

Participants received 120 mg of FGF402 and 300 mg of PDR001 while fasted

Reporting group title	All Patients Combination

Reporting group description:

This group comprised of all participants who took combination treatment of FGF401 and PDR001

Reporting group title	All Patients

Reporting group description:

These are all the participants in the study

Serious adverse events	Phase I Part 50 mg Fasted	Phase I Part 80 mg Fasted	Phase I Part 80 mg Fed
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 11 (27.27%)	5 / 6 (83.33%)	3 / 5 (60.00%)
number of deaths (all causes)	2	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Liver carcinoma ruptured			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (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
Vascular disorders			
Aneurysm			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena caval occlusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (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, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchostenosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (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
Dyspnoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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			
Bone contusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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			
Carotid artery stenosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ascites			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (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 varices haemorrhage			

subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 11 (9.09%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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			
Biloma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 cirrhosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 haematoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 pain			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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			
Hypercalcaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (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
Hyperglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
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	Phase I Part 120 mg Fasted	Phase I Part 120 mg Fed	Phase I Part 150 mg Fasted
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 26 (57.69%)	9 / 19 (47.37%)	3 / 7 (42.86%)
number of deaths (all causes)	4	6	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Liver carcinoma ruptured			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 associated fever			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour thrombosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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			
Aneurysm			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bleeding varicose vein			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inferior vena caval occlusion			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Venous thrombosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest discomfort			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (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
Gait disturbance			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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			
Atelectasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchial obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchostenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (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
Pneumonitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Productive cough			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (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
Psychiatric disorders			

Confusional state			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (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
Nervous system disorders			
Carotid artery stenosis			

subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Paraparesis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraplegia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (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
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	3 / 19 (15.79%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	2 / 26 (7.69%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Duodenal obstruction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	0 / 7 (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
Haematemesis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (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
Vomiting			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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			
Biloma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			

subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Cholestasis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Hepatic cirrhosis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Hepatic haematoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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 pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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 and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (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
Calculus urinary			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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			
Back pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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			
Herpes zoster			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
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			
Hypercalcaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperglycaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (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

Serious adverse events	Phase II Part Group 1	Phase II Part Group 2	Phase II Part Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 30 (50.00%)	9 / 36 (25.00%)	8 / 20 (40.00%)
number of deaths (all causes)	2	2	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Liver carcinoma ruptured			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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
Tumour associated fever			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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			
Aneurysm			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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
Bleeding varicose vein			

subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Hypovolaemic shock			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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
Inferior vena caval occlusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Chest discomfort			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Fatigue			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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
Oedema peripheral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 36 (0.00%)	2 / 20 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Bronchial obstruction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchostenosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Productive cough			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Blood bilirubin increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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

Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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			
Carotid artery stenosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			

subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Paraplegia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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	0 / 30 (0.00%)	2 / 36 (5.56%)	3 / 20 (15.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ascites			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric varices			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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 varices haemorrhage			

subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biloma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Cholestasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 cirrhosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 haematoma			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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 pain			

subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	0 / 20 (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
Infections and infestations			
Herpes zoster			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Lung infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (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
Pyelonephritis acute			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (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
Varicella			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
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	All Patients Single agent	Phase I Part FGF401 80 mg + PDR001 300 mg	Phase I Part FGF401 120 mg + PDR001 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	70 / 160 (43.75%)	0 / 6 (0.00%)	2 / 6 (33.33%)
number of deaths (all causes)	20	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Liver carcinoma ruptured			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Tumour thrombosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Vascular disorders			
Aneurysm			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Bleeding varicose vein			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Hypovolaemic shock			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Inferior vena caval occlusion			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Venous thrombosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Chest discomfort			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Fatigue			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Gait disturbance			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Oedema peripheral			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Pyrexia			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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

Bronchial obstruction			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Bronchostenosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Dyspnoea			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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
Haemoptysis			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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
Pneumonitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Productive cough			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Pulmonary embolism			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Psychiatric disorders			

Confusional state			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Coronary artery disease			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Nervous system disorders			
Carotid artery stenosis			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Cerebrovascular accident			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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 / 160 (0.63%)	0 / 6 (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
Haemorrhage intracranial			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Paraesthesia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Paraparesis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Paraplegia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	9 / 160 (5.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Dysphagia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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 varices			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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 / 1	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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
Haematemesis			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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			
Biloma			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Cholangitis			

subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Hepatic cirrhosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Hepatic haematoma			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Hepatic pain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Hyperbilirubinaemia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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
Calculus urinary			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Urinary retention			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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 and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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
Infections and infestations			
Herpes zoster			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Lung infection			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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
Pneumonia			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Varicella			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (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
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperglycaemia			
subjects affected / exposed	0 / 160 (0.00%)	0 / 6 (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
Hypoglycaemia			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (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

Serious adverse events	All Patients Combination	All Patients	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 12 (16.67%)	72 / 172 (41.86%)	
number of deaths (all causes)	0	20	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Liver carcinoma ruptured			
subjects affected / exposed	1 / 12 (8.33%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour associated fever			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aneurysm			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bleeding varicose vein			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inferior vena caval occlusion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	2 / 12 (16.67%)	5 / 172 (2.91%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Atelectasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial obstruction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchostenosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			

subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraparesis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraplegia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	9 / 172 (5.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ascites			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	2 / 12 (16.67%)	3 / 172 (1.74%)	
occurrences causally related to treatment / all	1 / 2	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric varices			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			

subjects affected / exposed	1 / 12 (8.33%)	3 / 172 (1.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biloma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholestasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic haematoma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Phase I Part 50 mg Fasted	Phase I Part 80 mg Fasted	Phase I Part 80 mg Fed
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 11 (100.00%)	6 / 6 (100.00%)	5 / 5 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pyogenic granuloma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Inferior vena cava syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Venous thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 11 (18.18%)	2 / 6 (33.33%)	0 / 5 (0.00%)
occurrences (all)	3	3	0
Chest discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Face oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 11 (18.18%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Gait disturbance			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 11 (27.27%)	0 / 6 (0.00%)	2 / 5 (40.00%)
occurrences (all)	6	0	2
Vessel puncture site bruise			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Female genital tract fistula			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Varicocele			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchostenosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 11 (9.09%)	1 / 6 (16.67%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Dyspnoea exertional			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Epistaxis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lung disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Orthopnoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sputum increased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Bulimia nervosa			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Emotional disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Nightmare			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	3 / 11 (27.27%)	3 / 6 (50.00%)	2 / 5 (40.00%)
occurrences (all)	3	6	5
Alpha 1 foetoprotein increased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 11 (36.36%)	3 / 6 (50.00%)	2 / 5 (40.00%)
occurrences (all)	6	4	3
Bacterial test positive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Blood bilirubin increased			
subjects affected / exposed	4 / 11 (36.36%)	3 / 6 (50.00%)	1 / 5 (20.00%)
occurrences (all)	5	3	2
Blood cholesterol increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Blood creatinine increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Blood lactate dehydrogenase increased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	1 / 5 (20.00%)
occurrences (all)	0	1	2
Lymphocyte count decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Prothrombin time prolonged			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fracture			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periorbital haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post procedural discharge			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cyanosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Ventricular extrasystoles			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cervical radiculopathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	3 / 11 (27.27%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Headache			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Hemiparesis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Paraparesis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyperglobulinaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Leukopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Autophony			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vestibular disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye swelling			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	3 / 5 (60.00%)
occurrences (all)	0	1	3
Abdominal pain lower			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 11 (9.09%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Abdominal tenderness			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Aerophagia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	2 / 5 (40.00%)
occurrences (all)	0	2	2
Chronic gastritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Dental caries			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	8 / 11 (72.73%)	4 / 6 (66.67%)	4 / 5 (80.00%)
occurrences (all)	16	5	8
Dry mouth			

subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Duodenal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Duodenitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Eructation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastric disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastric ulcer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal sounds abnormal			

subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 11 (9.09%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	2	1	0
Oesophageal stenosis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oesophageal ulcer			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Oesophagitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Proctalgia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 11 (18.18%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Toothache			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 11 (9.09%)	1 / 6 (16.67%)	1 / 5 (20.00%)
occurrences (all)	1	1	1
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hepatic pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hepatocellular injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hepatomegaly			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatorenal syndrome			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0

Hyperbilirubinaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Jaundice cholestatic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ecchymosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 11 (18.18%)	2 / 6 (33.33%)	1 / 5 (20.00%)
occurrences (all)	3	2	1
Rash			
subjects affected / exposed	1 / 11 (9.09%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Rash macular			

subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Contracted bladder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neurogenic bladder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Proteinuria			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Cortisol deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Spinal pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Folliculitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Helicobacter infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hepatitis B			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea capitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vulvitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	3 / 11 (27.27%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	3	1	0
Dyslipidaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 11 (9.09%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	1	3	0
Hyperglycaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	3
Hyperlipasaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Hyperphosphataemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 11 (9.09%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 6 (16.67%)	1 / 5 (20.00%)
occurrences (all)	0	1	2
Hypophosphataemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 6 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase I Part 120 mg Fasted	Phase I Part 120 mg Fed	Phase I Part 150 mg Fasted
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 26 (100.00%)	19 / 19 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyogenic granuloma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	4
Hypotension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Inferior vena cava syndrome			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vascular compression			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vena cava thrombosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 26 (15.38%)	3 / 19 (15.79%)	2 / 7 (28.57%)
occurrences (all)	5	4	2
Chest discomfort			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 26 (23.08%)	4 / 19 (21.05%)	0 / 7 (0.00%)
occurrences (all)	6	5	0
Gait disturbance			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hernia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	9 / 26 (34.62%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	10	0	0
Pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	6 / 26 (23.08%)	1 / 19 (5.26%)	1 / 7 (14.29%)
occurrences (all)	8	1	1
Vessel puncture site bruise			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Female genital tract fistula			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oedema genital			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scrotal oedema			

subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Varicocele			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Bronchostenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 26 (7.69%)	2 / 19 (10.53%)	2 / 7 (28.57%)
occurrences (all)	3	2	2
Dysphonia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	3 / 26 (11.54%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lung disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Orthopnoea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sputum increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bulimia nervosa			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Depression			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Emotional disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Nightmare			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	14 / 26 (53.85%)	11 / 19 (57.89%)	7 / 7 (100.00%)
occurrences (all)	19	13	11
Alpha 1 foetoprotein increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	16 / 26 (61.54%)	14 / 19 (73.68%)	7 / 7 (100.00%)
occurrences (all)	22	20	13
Bacterial test positive			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bilirubin conjugated increased			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 26 (15.38%)	5 / 19 (26.32%)	1 / 7 (14.29%)
occurrences (all)	6	5	1
Blood bilirubin increased			
subjects affected / exposed	11 / 26 (42.31%)	2 / 19 (10.53%)	0 / 7 (0.00%)
occurrences (all)	16	2	0
Blood cholesterol increased			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 26 (3.85%)	2 / 19 (10.53%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Blood creatinine increased			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 26 (15.38%)	2 / 19 (10.53%)	0 / 7 (0.00%)
occurrences (all)	5	2	0
Haemoglobin decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	1 / 26 (3.85%)	2 / 19 (10.53%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Weight increased			

subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
White blood cell count increased			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Bone contusion			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Clavicle fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Humerus fracture			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Joint dislocation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital haemorrhage			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post procedural discharge			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Bradycardia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Cyanosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Aphonia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cervical radiculopathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraparesis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seizure			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal cord compression			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Visual field defect			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 26 (11.54%)	2 / 19 (10.53%)	1 / 7 (14.29%)
occurrences (all)	5	2	1
Hyperglobulinaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Lymph node pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	1	1	0

Ear and labyrinth disorders			
Autophony			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vestibular disorder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Eye swelling			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	3 / 26 (11.54%)	0 / 19 (0.00%)	3 / 7 (42.86%)
occurrences (all)	4	0	3
Abdominal pain			
subjects affected / exposed	3 / 26 (11.54%)	4 / 19 (21.05%)	0 / 7 (0.00%)
occurrences (all)	3	5	0
Abdominal pain lower			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	7 / 26 (26.92%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	8	1	0
Abdominal tenderness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aerophagia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anal incontinence			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	5 / 26 (19.23%)	0 / 19 (0.00%)	2 / 7 (28.57%)
occurrences (all)	5	0	2
Chronic gastritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	4 / 26 (15.38%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Dental caries			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	18 / 26 (69.23%)	14 / 19 (73.68%)	7 / 7 (100.00%)
occurrences (all)	25	19	8
Dry mouth			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Duodenal obstruction			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Duodenal ulcer			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Duodenitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastric disorder			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastric ulcer			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	4 / 26 (15.38%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Haematemesis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Nausea			
subjects affected / exposed	5 / 26 (19.23%)	6 / 19 (31.58%)	1 / 7 (14.29%)
occurrences (all)	5	6	2
Oesophageal stenosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal ulcer			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Varices oesophageal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	4 / 26 (15.38%)	6 / 19 (31.58%)	1 / 7 (14.29%)
occurrences (all)	4	8	1
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatocellular injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hepatorenal syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Jaundice			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Jaundice cholestatic			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Portal vein thrombosis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	4 / 26 (15.38%)	5 / 19 (26.32%)	1 / 7 (14.29%)
occurrences (all)	4	5	1
Rash			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rosacea			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Contracted bladder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Leukocyturia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neurogenic bladder			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Cortisol deficiency			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Flank pain			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	3 / 26 (11.54%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Myalgia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Osteoporosis			

subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatitis B			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Herpes zoster			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lung infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Oral candidiasis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periodontitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash pustular			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	2 / 26 (7.69%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	2	1	0

Sinusitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea capitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Vulvitis			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	10 / 26 (38.46%)	2 / 19 (10.53%)	4 / 7 (57.14%)
occurrences (all)	10	2	4
Dyslipidaemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Hyperglycaemia			

subjects affected / exposed	1 / 26 (3.85%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Hyperkalaemia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperlipasaemia			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 26 (7.69%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	3 / 26 (11.54%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	3 / 26 (11.54%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	3 / 26 (11.54%)	2 / 19 (10.53%)	0 / 7 (0.00%)
occurrences (all)	3	2	0
Hypophosphataemia			
subjects affected / exposed	0 / 26 (0.00%)	1 / 19 (5.26%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			

subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	1 / 26 (3.85%)	0 / 19 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Vitamin D deficiency			
subjects affected / exposed	0 / 26 (0.00%)	0 / 19 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase II Part Group 1	Phase II Part Group 2	Phase II Part Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 30 (100.00%)	36 / 36 (100.00%)	20 / 20 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pyogenic granuloma			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Tumour associated fever			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Haematoma			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Hot flush			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 30 (0.00%)	3 / 36 (8.33%)	2 / 20 (10.00%)
occurrences (all)	0	5	2
Hypotension			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Inferior vena cava syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vena cava thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Venous thrombosis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 30 (10.00%)	6 / 36 (16.67%)	4 / 20 (20.00%)
occurrences (all)	4	14	8
Chest discomfort			
subjects affected / exposed	2 / 30 (6.67%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Chest pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	3 / 30 (10.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	3
Face oedema			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Fatigue			

subjects affected / exposed	2 / 30 (6.67%)	8 / 36 (22.22%)	7 / 20 (35.00%)
occurrences (all)	2	10	9
Gait disturbance			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
General physical health deterioration			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Hernia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Injection site pruritus			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Localised oedema			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	8 / 30 (26.67%)	9 / 36 (25.00%)	3 / 20 (15.00%)
occurrences (all)	8	10	3
Pain			

subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Peripheral swelling			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	9 / 30 (30.00%)	4 / 36 (11.11%)	5 / 20 (25.00%)
occurrences (all)	13	5	12
Vessel puncture site bruise			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Female genital tract fistula			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Scrotal oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Varicocele			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchostenosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cough			

subjects affected / exposed	7 / 30 (23.33%)	3 / 36 (8.33%)	2 / 20 (10.00%)
occurrences (all)	8	4	2
Dysphonia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	4 / 30 (13.33%)	3 / 36 (8.33%)	3 / 20 (15.00%)
occurrences (all)	5	3	4
Dyspnoea exertional			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Haemoptysis			
subjects affected / exposed	3 / 30 (10.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	3	0	0
Hiccups			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Lung disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 30 (6.67%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Orthopnoea			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Pneumonitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	3 / 30 (10.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	3	1	0
Pulmonary oedema			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 30 (3.33%)	2 / 36 (5.56%)	1 / 20 (5.00%)
occurrences (all)	1	2	2
Bulimia nervosa			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Emotional disorder			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	4 / 30 (13.33%)	2 / 36 (5.56%)	5 / 20 (25.00%)
occurrences (all)	4	2	5
Nightmare			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1

Sleep disorder			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Alanine aminotransferase increased			
subjects affected / exposed	13 / 30 (43.33%)	11 / 36 (30.56%)	6 / 20 (30.00%)
occurrences (all)	16	12	8
Alpha 1 foetoprotein increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 30 (3.33%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	1	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	14 / 30 (46.67%)	11 / 36 (30.56%)	5 / 20 (25.00%)
occurrences (all)	15	14	9
Bacterial test positive			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Bilirubin conjugated increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 30 (13.33%)	2 / 36 (5.56%)	2 / 20 (10.00%)
occurrences (all)	5	2	2
Blood bilirubin increased			
subjects affected / exposed	6 / 30 (20.00%)	3 / 36 (8.33%)	1 / 20 (5.00%)
occurrences (all)	7	3	1
Blood cholesterol increased			

subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 30 (3.33%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 30 (13.33%)	3 / 36 (8.33%)	3 / 20 (15.00%)
occurrences (all)	4	3	3
Haemoglobin decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Lipase increased			

subjects affected / exposed	4 / 30 (13.33%)	6 / 36 (16.67%)	1 / 20 (5.00%)
occurrences (all)	5	6	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Neutrophil count decreased			
subjects affected / exposed	2 / 30 (6.67%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Platelet count decreased			
subjects affected / exposed	2 / 30 (6.67%)	2 / 36 (5.56%)	1 / 20 (5.00%)
occurrences (all)	2	2	1
Prothrombin time prolonged			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Weight decreased			
subjects affected / exposed	0 / 30 (0.00%)	4 / 36 (11.11%)	4 / 20 (20.00%)
occurrences (all)	0	4	4
Weight increased			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
White blood cell count increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			

subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Face injury			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Fracture			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Humerus fracture			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Periorbital haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Post procedural discharge			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	5 / 30 (16.67%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	5	0	1
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Cyanosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Aphonia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Cervical radiculopathy			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	2 / 30 (6.67%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Dysgeusia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	1	1	1
Headache			
subjects affected / exposed	4 / 30 (13.33%)	3 / 36 (8.33%)	3 / 20 (15.00%)
occurrences (all)	4	3	3
Hemiparesis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Hypotonia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Memory impairment			

subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Paraparesis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Seizure			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Spinal cord compression			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Taste disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	5 / 30 (16.67%)	1 / 36 (2.78%)	5 / 20 (25.00%)
occurrences (all)	5	1	5
Hyperglobulinaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Leukopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Autophony			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Vestibular disorder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Eye swelling			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	3 / 30 (10.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	3	1	1
Abdominal pain			
subjects affected / exposed	5 / 30 (16.67%)	6 / 36 (16.67%)	9 / 20 (45.00%)
occurrences (all)	5	8	12
Abdominal pain lower			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	5 / 30 (16.67%)	5 / 36 (13.89%)	1 / 20 (5.00%)
occurrences (all)	6	8	1
Abdominal tenderness			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Aerophagia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Anal incontinence			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Angular cheilitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	4 / 30 (13.33%)	3 / 36 (8.33%)	2 / 20 (10.00%)
occurrences (all)	4	3	2
Chronic gastritis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Constipation			
subjects affected / exposed	5 / 30 (16.67%)	5 / 36 (13.89%)	6 / 20 (30.00%)
occurrences (all)	5	6	8
Dental caries			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	23 / 30 (76.67%)	23 / 36 (63.89%)	17 / 20 (85.00%)
occurrences (all)	42	44	35
Dry mouth			
subjects affected / exposed	0 / 30 (0.00%)	3 / 36 (8.33%)	1 / 20 (5.00%)
occurrences (all)	0	4	1
Duodenal obstruction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Duodenal ulcer			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Duodenitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 30 (0.00%)	4 / 36 (11.11%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Dysphagia			
subjects affected / exposed	1 / 30 (3.33%)	2 / 36 (5.56%)	1 / 20 (5.00%)
occurrences (all)	1	2	1
Eructation			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastric disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Gastric ulcer			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Haematemesis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Haematochezia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	4
Haemorrhoids			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	2 / 30 (6.67%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	7 / 30 (23.33%)	6 / 36 (16.67%)	11 / 20 (55.00%)
occurrences (all)	7	8	14
Oesophageal stenosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Oesophageal ulcer			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Proctalgia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Varices oesophageal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	5 / 30 (16.67%)	4 / 36 (11.11%)	9 / 20 (45.00%)
occurrences (all)	9	8	11
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			

subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Hepatocellular injury			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	2
Hepatomegaly			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatorenal syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Jaundice			
subjects affected / exposed	2 / 30 (6.67%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Jaundice cholestatic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	0 / 30 (0.00%)	4 / 36 (11.11%)	2 / 20 (10.00%)
occurrences (all)	0	5	2
Ecchymosis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 30 (0.00%)	3 / 36 (8.33%)	0 / 20 (0.00%)
occurrences (all)	0	3	0

Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 30 (3.33%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Pruritus			
subjects affected / exposed	5 / 30 (16.67%)	8 / 36 (22.22%)	0 / 20 (0.00%)
occurrences (all)	5	10	0
Rash			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	2 / 20 (10.00%)
occurrences (all)	1	0	2
Rash macular			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rosacea			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Skin fissures			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	4	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Contracted bladder			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Leukocyturia			

subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Neurogenic bladder			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Cortisol deficiency			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hyperthyroidism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	1 / 20 (5.00%)
occurrences (all)	0	3	1
Back pain			
subjects affected / exposed	5 / 30 (16.67%)	4 / 36 (11.11%)	1 / 20 (5.00%)
occurrences (all)	5	4	1
Flank pain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Groin pain			

subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	1 / 20 (5.00%)
occurrences (all)	0	2	1
Muscular weakness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Musculoskeletal pain			
subjects affected / exposed	3 / 30 (10.00%)	2 / 36 (5.56%)	3 / 20 (15.00%)
occurrences (all)	3	3	3
Myalgia			
subjects affected / exposed	3 / 30 (10.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	3	0	1
Neck pain			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Osteoporosis			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Pain in extremity			
subjects affected / exposed	2 / 30 (6.67%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Spinal pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Anal abscess			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0

Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Candida infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Helicobacter infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatitis B			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	1 / 30 (3.33%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Hordeolum			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Infected dermal cyst			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	1 / 30 (3.33%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	1	1	0

Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	1	3	0
Oral candidiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Oral fungal infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Periodontitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Rash pustular			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	1 / 20 (5.00%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	2
Tinea capitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Tinea cruris			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Tinea versicolour			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Vulvitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	6 / 30 (20.00%)	9 / 36 (25.00%)	12 / 20 (60.00%)
occurrences (all)	6	10	12
Dyslipidaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	1	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	2	0
Hyperlipasaemia			
subjects affected / exposed	0 / 30 (0.00%)	2 / 36 (5.56%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Hyperphosphataemia			
subjects affected / exposed	3 / 30 (10.00%)	1 / 36 (2.78%)	2 / 20 (10.00%)
occurrences (all)	5	1	2
Hypertriglyceridaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			

subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	7 / 30 (23.33%)	1 / 36 (2.78%)	2 / 20 (10.00%)
occurrences (all)	8	1	3
Hypocalcaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	3	0
Hypomagnesaemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 36 (0.00%)	1 / 20 (5.00%)
occurrences (all)	1	0	1
Iron deficiency			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Malnutrition			
subjects affected / exposed	0 / 30 (0.00%)	0 / 36 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 30 (0.00%)	1 / 36 (2.78%)	0 / 20 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	All Patients Single agent	Phase I Part FGF401 80 mg + PDR001 300 mg	Phase I Part FGF401 120 mg + PDR001 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	160 / 160 (100.00%)	6 / 6 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Basal cell carcinoma			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cancer pain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pyogenic granuloma			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tumour associated fever			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haematoma			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hot flush			
subjects affected / exposed	0 / 160 (0.00%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Hypertension			
subjects affected / exposed	9 / 160 (5.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	13	0	0
Hypotension			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Inferior vena cava syndrome			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vascular compression			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vena cava thrombosis			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Venous thrombosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	26 / 160 (16.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	43	0	0
Chest discomfort			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Chest pain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	7	0	0
Face oedema			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	30 / 160 (18.75%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	35	1	2
Gait disturbance			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
General physical health deterioration			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hernia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Injection site pruritus			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Malaise			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	2 / 160 (1.25%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Oedema peripheral			
subjects affected / exposed	30 / 160 (18.75%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	33	0	3
Pain			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Peripheral swelling			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Pyrexia			
subjects affected / exposed	31 / 160 (19.38%)	1 / 6 (16.67%)	3 / 6 (50.00%)
occurrences (all)	48	1	3
Vessel puncture site bruise			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast			

disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Female genital tract fistula			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oedema genital			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pelvic pain			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Scrotal oedema			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Varicocele			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchostenosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	19 / 160 (11.88%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	22	0	2
Dysphonia			
subjects affected / exposed	2 / 160 (1.25%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
subjects affected / exposed	17 / 160 (10.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	19	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Epistaxis			

subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Haemoptysis			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Hiccups			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Lung disorder			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Orthopnoea			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Pneumonitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Productive cough			
subjects affected / exposed	6 / 160 (3.75%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	6	0	1
Pulmonary oedema			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sputum increased			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	7	0	0
Bulimia nervosa			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Emotional disorder			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	16 / 160 (10.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	16	0	1
Nightmare			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Alanine aminotransferase increased			
subjects affected / exposed	70 / 160 (43.75%)	0 / 6 (0.00%)	4 / 6 (66.67%)
occurrences (all)	93	0	4
Alpha 1 foetoprotein increased			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Amylase increased			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	76 / 160 (47.50%)	1 / 6 (16.67%)	5 / 6 (83.33%)
occurrences (all)	106	1	6
Bacterial test positive			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Bilirubin conjugated increased			
subjects affected / exposed	0 / 160 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed	1 / 160 (0.63%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	20 / 160 (12.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	23	0	1
Blood bilirubin increased			
subjects affected / exposed	31 / 160 (19.38%)	1 / 6 (16.67%)	2 / 6 (33.33%)
occurrences (all)	39	1	2
Blood cholesterol increased			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	8	0	1
Blood creatinine increased			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	6	0	1
Blood lactate dehydrogenase increased			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 160 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Blood uric acid increased			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	17 / 160 (10.63%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	18	1	1
Haemoglobin decreased			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
International normalised ratio increased			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	14 / 160 (8.75%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	17	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Neutrophil count decreased			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	2	0	3
Platelet count decreased			

subjects affected / exposed	6 / 160 (3.75%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	6	0	2
Prothrombin time prolonged			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Transaminases increased			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Weight decreased			
subjects affected / exposed	12 / 160 (7.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	12	0	1
Weight increased			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
White blood cell count increased			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Bone contusion			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Clavicle fracture			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Face injury			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Fracture			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Humerus fracture			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Joint dislocation			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Periorbital haemorrhage			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Post procedural discharge			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	7 / 160 (4.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	7	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Bradycardia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cyanosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	1 / 160 (0.63%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Sinus tachycardia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Ventricular extrasystoles			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Aphonia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cervical radiculopathy			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Dysgeusia			
subjects affected / exposed	6 / 160 (3.75%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	6	0	1
Headache			
subjects affected / exposed	12 / 160 (7.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	12	0	1
Hemiparesis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypotonia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Memory impairment			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Paraparesis			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 160 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Post herpetic neuralgia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Seizure			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Spinal cord compression			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Taste disorder			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Visual field defect			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	18 / 160 (11.25%)	2 / 6 (33.33%)	2 / 6 (33.33%)
occurrences (all)	20	2	2
Hyperglobulinaemia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0

Leukopenia			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Lymph node pain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lymphopenia			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
Autophony			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Vestibular disorder			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Eye swelling			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	2 / 160 (1.25%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Abdominal distension			
subjects affected / exposed	13 / 160 (8.13%)	0 / 6 (0.00%)	3 / 6 (50.00%)
occurrences (all)	14	0	4
Abdominal pain			
subjects affected / exposed	31 / 160 (19.38%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	37	0	2
Abdominal pain lower			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	21 / 160 (13.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	26	0	0
Abdominal tenderness			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Aerophagia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Anal incontinence			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Angular cheilitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	19 / 160 (11.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	20	0	0
Chronic gastritis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	23 / 160 (14.38%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	26	1	0
Dental caries			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	118 / 160 (73.75%)	3 / 6 (50.00%)	4 / 6 (66.67%)
occurrences (all)	202	5	6
Dry mouth			

subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	6	0	0
Duodenal obstruction			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Duodenal ulcer			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Duodenitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Dysphagia			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Eructation			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastric disorder			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastric ulcer			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal sounds abnormal			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 160 (3.75%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	6	0	0
Haematemesis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Haematochezia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Haemorrhoids			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Melaena			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Nausea			
subjects affected / exposed	38 / 160 (23.75%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	45	0	3
Oesophageal stenosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oesophageal ulcer			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oesophagitis			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Proctalgia			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Toothache			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Varices oesophageal			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	32 / 160 (20.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	44	0	1
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatic pain			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Hepatocellular injury			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Hepatomegaly			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hepatorenal syndrome			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Hyperbilirubinaemia			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Jaundice			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Jaundice cholestatic			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Portal vein thrombosis			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	7 / 160 (4.38%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	8	1	0
Ecchymosis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	28 / 160 (17.50%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	31	0	4
Rash			
subjects affected / exposed	6 / 160 (3.75%)	0 / 6 (0.00%)	2 / 6 (33.33%)
occurrences (all)	6	0	4
Rash macular			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Rosacea			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Skin fissures			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Contracted bladder			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Leukocyturia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Neurogenic bladder			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Proteinuria			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Endocrine disorders			
Cortisol deficiency			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hyperthyroidism			
subjects affected / exposed	0 / 160 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 160 (1.88%)	1 / 6 (16.67%)	1 / 6 (16.67%)
occurrences (all)	4	1	1
Back pain			
subjects affected / exposed	14 / 160 (8.75%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	14	2	0
Flank pain			
subjects affected / exposed	3 / 160 (1.88%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Groin pain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Muscular weakness			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Musculoskeletal pain			

subjects affected / exposed	12 / 160 (7.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	13	0	0
Myalgia			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	4	0	1
Neck pain			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Osteoporosis			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Pain in extremity			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Spinal pain			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Anal abscess			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Candida infection			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 160 (0.00%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0

Helicobacter infection			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hepatitis B			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Herpes virus infection			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Herpes zoster			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hordeolum			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infected dermal cyst			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Lung infection			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 160 (3.13%)	2 / 6 (33.33%)	0 / 6 (0.00%)
occurrences (all)	6	2	0
Oral candidiasis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Oral fungal infection			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Pneumonia			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Rash pustular			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Sinusitis			
subjects affected / exposed	0 / 160 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Staphylococcal infection			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Tinea capitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Tinea cruris			
subjects affected / exposed	0 / 160 (0.00%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Tinea versicolour			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Vulvitis			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	47 / 160 (29.38%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	48	0	0
Dyslipidaemia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypercalcaemia			
subjects affected / exposed	4 / 160 (2.50%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	8	0	0
Hyperglycaemia			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	5	0	0
Hyperkalaemia			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	6	0	0
Hyperlipasaemia			
subjects affected / exposed	6 / 160 (3.75%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	8	0	0
Hyperphosphataemia			
subjects affected / exposed	8 / 160 (5.00%)	2 / 6 (33.33%)	3 / 6 (50.00%)
occurrences (all)	10	2	4
Hypertriglyceridaemia			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Hyperuricaemia			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	14 / 160 (8.75%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	16	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	5 / 160 (3.13%)	0 / 6 (0.00%)	1 / 6 (16.67%)
occurrences (all)	7	0	1
Hypomagnesaemia			

subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Hyponatraemia			
subjects affected / exposed	7 / 160 (4.38%)	1 / 6 (16.67%)	0 / 6 (0.00%)
occurrences (all)	8	1	0
Hypophosphataemia			
subjects affected / exposed	3 / 160 (1.88%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Iron deficiency			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Malnutrition			
subjects affected / exposed	2 / 160 (1.25%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 160 (0.63%)	0 / 6 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	All Patients Combination	All Patients	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	172 / 172 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Cancer pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Pyogenic granuloma			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Tumour associated fever			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Vascular disorders			

Deep vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Hot flush			
subjects affected / exposed	2 / 12 (16.67%)	2 / 172 (1.16%)	
occurrences (all)	2	2	
Hypertension			
subjects affected / exposed	0 / 12 (0.00%)	9 / 172 (5.23%)	
occurrences (all)	0	13	
Hypotension			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Inferior vena cava syndrome			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Vascular compression			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Vena cava thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Venous thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	26 / 172 (15.12%)	
occurrences (all)	0	43	
Chest discomfort			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Chest pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Chills			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	7	
Face oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	3 / 12 (25.00%)	33 / 172 (19.19%)	
occurrences (all)	3	38	
Gait disturbance			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
General physical health deterioration			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Hernia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Injection site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Localised oedema			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Mucosal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Non-cardiac chest pain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Oedema			
subjects affected / exposed	1 / 12 (8.33%)	3 / 172 (1.74%)	
occurrences (all)	1	3	
Oedema peripheral			
subjects affected / exposed	2 / 12 (16.67%)	32 / 172 (18.60%)	
occurrences (all)	3	36	
Pain			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	4	
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Pyrexia			
subjects affected / exposed	4 / 12 (33.33%)	35 / 172 (20.35%)	
occurrences (all)	4	52	
Vessel puncture site bruise			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Female genital tract fistula			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Oedema genital			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Pelvic pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Scrotal oedema			

subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Varicocele			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Bronchostenosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Cough			
subjects affected / exposed	1 / 12 (8.33%)	20 / 172 (11.63%)	
occurrences (all)	2	24	
Dysphonia			
subjects affected / exposed	1 / 12 (8.33%)	3 / 172 (1.74%)	
occurrences (all)	1	3	
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	17 / 172 (9.88%)	
occurrences (all)	0	19	
Dyspnoea exertional			
subjects affected / exposed	1 / 12 (8.33%)	2 / 172 (1.16%)	
occurrences (all)	1	2	
Epistaxis			
subjects affected / exposed	1 / 12 (8.33%)	3 / 172 (1.74%)	
occurrences (all)	1	3	
Haemoptysis			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	5	
Hiccups			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Lung disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Nasal congestion			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	4	
Orthopnoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Pleural effusion			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Pneumonitis			
subjects affected / exposed	1 / 12 (8.33%)	2 / 172 (1.16%)	
occurrences (all)	1	2	
Productive cough			
subjects affected / exposed	1 / 12 (8.33%)	7 / 172 (4.07%)	
occurrences (all)	1	7	
Pulmonary oedema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Sputum increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Wheezing			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	7	
Bulimia nervosa			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	

Depression			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Emotional disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	1 / 12 (8.33%)	17 / 172 (9.88%)	
occurrences (all)	1	17	
Nightmare			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Alanine aminotransferase increased			
subjects affected / exposed	4 / 12 (33.33%)	74 / 172 (43.02%)	
occurrences (all)	4	97	
Alpha 1 foetoprotein increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Amylase increased			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	4	
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 12 (50.00%)	82 / 172 (47.67%)	
occurrences (all)	7	113	
Bacterial test positive			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Bilirubin conjugated increased			

subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences (all)	1	1	
Blood albumin decreased			
subjects affected / exposed	1 / 12 (8.33%)	2 / 172 (1.16%)	
occurrences (all)	2	3	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 12 (8.33%)	21 / 172 (12.21%)	
occurrences (all)	1	24	
Blood bilirubin increased			
subjects affected / exposed	3 / 12 (25.00%)	34 / 172 (19.77%)	
occurrences (all)	3	42	
Blood cholesterol increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 12 (8.33%)	6 / 172 (3.49%)	
occurrences (all)	1	9	
Blood creatinine increased			
subjects affected / exposed	1 / 12 (8.33%)	5 / 172 (2.91%)	
occurrences (all)	1	7	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Blood phosphorus decreased			
subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences (all)	2	2	
Blood uric acid increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
C-reactive protein increased			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 12 (16.67%)	19 / 172 (11.05%)	
occurrences (all)	2	20	
Haemoglobin decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
International normalised ratio increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Lipase increased			
subjects affected / exposed	0 / 12 (0.00%)	14 / 172 (8.14%)	
occurrences (all)	0	17	
Lymphocyte count decreased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Neutrophil count decreased			
subjects affected / exposed	2 / 12 (16.67%)	4 / 172 (2.33%)	
occurrences (all)	3	5	
Platelet count decreased			
subjects affected / exposed	1 / 12 (8.33%)	7 / 172 (4.07%)	
occurrences (all)	2	8	
Prothrombin time prolonged			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Transaminases increased			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Weight decreased			
subjects affected / exposed	1 / 12 (8.33%)	13 / 172 (7.56%)	
occurrences (all)	1	13	
Weight increased			

subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
White blood cell count increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Bone contusion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Clavicle fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Face injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Fall			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Humerus fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Joint dislocation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Ligament sprain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Periorbital haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Post procedural discharge			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	7 / 172 (4.07%)	
occurrences (all)	0	7	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Bradycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Cyanosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Palpitations			
subjects affected / exposed	1 / 12 (8.33%)	2 / 172 (1.16%)	
occurrences (all)	1	2	
Sinus tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Ventricular extrasystoles			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Nervous system disorders			
Aphonia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Cervical radiculopathy			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Dizziness			

subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Dysgeusia			
subjects affected / exposed	1 / 12 (8.33%)	7 / 172 (4.07%)	
occurrences (all)	1	7	
Headache			
subjects affected / exposed	1 / 12 (8.33%)	13 / 172 (7.56%)	
occurrences (all)	1	13	
Hemiparesis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Hypotonia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Memory impairment			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Neuropathy peripheral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Paraparesis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences (all)	1	1	
Post herpetic neuralgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Seizure			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Spinal cord compression			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Taste disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Visual field defect			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 12 (33.33%)	22 / 172 (12.79%)	
occurrences (all)	4	24	
Hyperglobulinaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Leukopenia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Lymphopenia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Thrombocytopenia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	

Ear and labyrinth disorders			
Autophony			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Vestibular disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Eye disorders			
Eye swelling			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 12 (8.33%)	3 / 172 (1.74%)	
occurrences (all)	1	3	
Abdominal distension			
subjects affected / exposed	3 / 12 (25.00%)	16 / 172 (9.30%)	
occurrences (all)	4	18	
Abdominal pain			
subjects affected / exposed	2 / 12 (16.67%)	33 / 172 (19.19%)	
occurrences (all)	2	39	
Abdominal pain lower			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	21 / 172 (12.21%)	
occurrences (all)	0	26	
Abdominal tenderness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Aerophagia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Anal incontinence			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Angular cheilitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Ascites			
subjects affected / exposed	0 / 12 (0.00%)	19 / 172 (11.05%)	
occurrences (all)	0	20	
Chronic gastritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	1 / 12 (8.33%)	24 / 172 (13.95%)	
occurrences (all)	1	27	
Dental caries			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	7 / 12 (58.33%)	125 / 172 (72.67%)	
occurrences (all)	11	213	
Dry mouth			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	6	
Duodenal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Duodenal ulcer			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Duodenitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Dyspepsia			

subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	4	
Dysphagia			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	5	
Eructation			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Flatulence			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Gastric disorder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Gastric ulcer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Gastrointestinal sounds abnormal			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 12 (0.00%)	6 / 172 (3.49%)	
occurrences (all)	0	6	
Haematemesis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Haematochezia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Haemorrhoidal haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	4	
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Melaena			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	4	
Nausea			
subjects affected / exposed	2 / 12 (16.67%)	40 / 172 (23.26%)	
occurrences (all)	3	48	
Oesophageal stenosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Oesophageal ulcer			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Oesophagitis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Proctalgia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Salivary hypersecretion			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	4	
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Varices oesophageal			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	1 / 12 (8.33%)	33 / 172 (19.19%)	
occurrences (all)	1	45	
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Hepatic pain			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	5	
Hepatocellular injury			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	4	
Hepatomegaly			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Hepatorenal syndrome			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	5	
Jaundice			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Jaundice cholestatic			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Portal vein thrombosis			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Dry skin			
subjects affected / exposed	1 / 12 (8.33%)	8 / 172 (4.65%)	
occurrences (all)	1	9	
Ecchymosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Night sweats			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Pruritus			
subjects affected / exposed	2 / 12 (16.67%)	30 / 172 (17.44%)	
occurrences (all)	4	35	
Rash			
subjects affected / exposed	2 / 12 (16.67%)	8 / 172 (4.65%)	
occurrences (all)	4	10	
Rash macular			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Rash maculo-papular			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Rosacea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Skin fissures			

subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	4	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Contracted bladder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	5	
Leukocyturia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Neurogenic bladder			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Nocturia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Pollakiuria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Proteinuria			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Urinary retention			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Endocrine disorders			
Cortisol deficiency			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Hyperthyroidism			

subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)	5 / 172 (2.91%)	
occurrences (all)	2	6	
Back pain			
subjects affected / exposed	2 / 12 (16.67%)	16 / 172 (9.30%)	
occurrences (all)	2	16	
Flank pain			
subjects affected / exposed	1 / 12 (8.33%)	4 / 172 (2.33%)	
occurrences (all)	2	5	
Groin pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Muscular weakness			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Musculoskeletal pain			
subjects affected / exposed	0 / 12 (0.00%)	12 / 172 (6.98%)	
occurrences (all)	0	13	
Myalgia			
subjects affected / exposed	1 / 12 (8.33%)	5 / 172 (2.91%)	
occurrences (all)	1	5	
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Osteoporosis			

subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Spinal pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Tendonitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Candida infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Folliculitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences (all)	1	1	
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Helicobacter infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Hepatitis B			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Herpes virus infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	

Herpes zoster			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Infected dermal cyst			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Lung infection			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Nasopharyngitis			
subjects affected / exposed	2 / 12 (16.67%)	7 / 172 (4.07%)	
occurrences (all)	2	8	
Oral candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Oral fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Periodontitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	4	
Rash pustular			
subjects affected / exposed	1 / 12 (8.33%)	2 / 172 (1.16%)	
occurrences (all)	1	2	
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	5	

Sinusitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences (all)	1	1	
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Staphylococcal infection			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Tinea capitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Tinea cruris			
subjects affected / exposed	1 / 12 (8.33%)	1 / 172 (0.58%)	
occurrences (all)	1	1	
Tinea versicolour			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	5	
Vulvitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	47 / 172 (27.33%)	
occurrences (all)	0	48	
Dyslipidaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Hypercalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	4 / 172 (2.33%)	
occurrences (all)	0	8	
Hyperglycaemia			

subjects affected / exposed	0 / 12 (0.00%)	5 / 172 (2.91%)	
occurrences (all)	0	5	
Hyperkalaemia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	6	
Hyperlipasaemia			
subjects affected / exposed	0 / 12 (0.00%)	6 / 172 (3.49%)	
occurrences (all)	0	8	
Hyperphosphataemia			
subjects affected / exposed	5 / 12 (41.67%)	13 / 172 (7.56%)	
occurrences (all)	6	16	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Hyperuricaemia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Hypoalbuminaemia			
subjects affected / exposed	0 / 12 (0.00%)	14 / 172 (8.14%)	
occurrences (all)	0	16	
Hypocalcaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	1 / 12 (8.33%)	6 / 172 (3.49%)	
occurrences (all)	1	8	
Hypomagnesaemia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	2	
Hyponatraemia			
subjects affected / exposed	1 / 12 (8.33%)	8 / 172 (4.65%)	
occurrences (all)	1	9	
Hypophosphataemia			
subjects affected / exposed	0 / 12 (0.00%)	3 / 172 (1.74%)	
occurrences (all)	0	3	
Iron deficiency			

subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Malnutrition			
subjects affected / exposed	0 / 12 (0.00%)	2 / 172 (1.16%)	
occurrences (all)	0	2	
Vitamin D deficiency			
subjects affected / exposed	0 / 12 (0.00%)	1 / 172 (0.58%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 October 2014	Issued 11 weeks before study start, the rationale for the amendment was to comply with health authority request to update the definition of Grade 3 diarrhea and Grade 3 hypercalcemia based on the NCI CTCAE.
18 November 2014	Issued 6 weeks before study start, the rationale for the amendment was to comply with the health authority suggestion to include the following: clarification of the starting dose planned for exploratory food effect cohort, clarification of the prophylactic treatment with anti-emetics in Cycle 1. For Japan only: specification of the informed consent procedure when subject was under the age of 20 years, specification of the additional ECG collection on Cycle 1 Day 1 for Japanese subjects only.
07 January 2015	Issued one week after study start, the purpose of this amendment was to add the amylase and lipase measurements to the local chemistry laboratory parameters collection plan in order to align with the criteria for dose-limiting toxicities specified in the protocol.
06 December 2016	Issued 101 weeks after study start, the primary purpose of this amendment was to add a combination treatment of FGF401 and PDR001, a humanized anti-programmed death-1 (PD-1) IgG4 antibody, in subjects with advanced hepatocellular carcinoma. In addition, the FGFR4/KLB/FGF19 molecular screening selection requirement for HCC subjects in the Phase II part of the FGF401 single agent was removed.
27 September 2018	Issued 195 weeks after study start, the main purposes of this amendment were: to incorporate health authority-requested language requiring study treatment discontinuation in the event of Stevens-Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN) (already implemented as part of an urgent safety measure released on 15-Jun-2018 due to an event in another study with PDR001 that did not involve FGF401) and to reduce study visits and assessments to ease the burden on patients who have been on study for more than 7 cycles, while maintaining access to study treatment and monitoring safety.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.nov for complete trial results.

Notes: