



Clinical trial results:

An Open-label, First-in-Human Study of the Safety, Tolerability, and Pharmacokinetics of VX-970/M6620 in Combination with Cytotoxic Chemotherapy in Participants With Advanced Solid Tumors

Summary

EudraCT number	2012-003126-25
Trial protocol	GB
Global end of trial date	11 March 2020

Results information

Result version number	v1 (current)
This version publication date	21 March 2021
First version publication date	21 March 2021

Trial information

Trial identification

Sponsor protocol code	MS201923-0001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02157792
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck KGaA, Darmstadt, Germany
Sponsor organisation address	Frankfurter Strasse 250, Darmstadt, Germany, 64293
Public contact	Communication Centre, Merck KGaA, Darmstadt, Germany, +49 6151725200, service@merckgroup.com
Scientific contact	Communication Center, Merck KGaA, Darmstadt, Germany, +49 6151725200, service@merckgroup.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	11 March 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the safety and tolerability of multiple ascending doses of intravenously administered M6620 in combination with gemcitabine, and in combination with cisplatin and gemcitabine, in subjects with advanced solid tumors.

Protection of trial subjects:

Subject protection was ensured by following high medical and ethical standards in accordance with the principles laid down in the Declaration of Helsinki, and that are consistent with Good Clinical Practice and applicable regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 December 2012
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	United Kingdom: 118
Country: Number of subjects enrolled	United States: 79
Worldwide total number of subjects	197
EEA total number of subjects	0

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)	134
From 65 to 84 years	63
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

First subject signed informed consent: 10 Dec 2012, Last subject last visit: 11 Mar 2020.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²

Arm description:

Subjects received intravenous infusion of M6620 at a initial dose of 18 milligrams per square meter (mg/m²) approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at a initial dose of 18 milligrams per square meter (mg/m²) approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 in combination with M6620.

Arm title	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at escalated dose of 36 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at escalated dose of 36 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 in combination with M6620.	
Arm title	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
Arm description:	
Subjects received intravenous infusion of M6620 at escalated dose of 60 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of M6620 at escalated dose of 60 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 in combination with M6620.	
Arm title	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Arm description:	
Subjects received intravenous infusion of M6620 at escalated dose of 72 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of M6620 at escalated dose of 72 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.	
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 in combination with M6620.	
Arm title	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²

Arm description:

Subjects received intravenous infusion of M6620 at escalated dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 in combination with M6620.

Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at escalated dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.

Arm title	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at escalated dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at dose of 500 mg/m² on Days 1 and 8 in combination with M6620.

Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at escalated dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.

Arm title	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 in combination with M6620.

Arm title	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 750 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 750 mg/m² on Days 1 and 8 in combination with M6620.

Arm title	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 in combination with M6620.

Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24

hours later on Days 2 and 9 in combination with Gemcitabine.

Arm title	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 1000 mg/m² on Days 1 and 8 in combination with M6620.

Arm title	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin
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Arm description:

Subjects received intravenous infusion of M6620 at dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 and 60 mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 41 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine and Cisplatin.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 in combination with M6620 and Cisplatin.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion

Routes of administration	Intravenous use
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Dosage and administration details:

Subjects received intravenous infusion of Cisplatin at a dose 60 mg/m² on Day 1 in combination with M6620 and Gemcitabine.

Arm title	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
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Arm description:

Subjects received intravenous infusion of M6620 at dose of 120 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 and 60 mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 41 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at dose of 120 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine and Cisplatin.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Cisplatin at a dose of 60 mg/m² on Day 1 in combination with M6620 and Gemcitabine.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 in combination with M6620 and Cisplatin.

Arm title	Part B1: M6620 140 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 of a 21-day cycle up to 74 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9.

Arm title	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 74 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Cisplatin at a dose of 40 mg/m² of on Day 1 in combination with M6620.

Arm title	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at dose of 140mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at dose of 140mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of 40 mg/m² of Cisplatin on Day 1 in combination with M6620.

Arm title	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of Cisplatin at a dose of 40 mg/m ² of on Day 1 in combination with M6620.	
Arm title	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²
Arm description:	
Subjects received intravenous infusion of M6620 at dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with 60 mg/m ² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.	
Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of M6620 at dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin.	
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of Cisplatin at a dose of 60 mg/m ² of on Day 1 in combination with M6620.	
Arm title	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Arm description:	
Subjects received intravenous infusion of M6620 at dose of 140 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with 75 mg/m ² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.	
Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of M6620 at dose of 140 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin.	
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details:	
Subjects received intravenous infusion of Cisplatin at a dose of 75 mg/m ² on Day 1 in combination with M6620.	
Arm title	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²

Arm description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 75 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of Cisplatin at a dose of 75 mg/m² of on Day 1 in combination with M6620.

Arm title	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at a dose of 60 mg/m², in combination with irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at a dose of 60 mg/m², in combination with irinotecan.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 in combination with M6620.

Arm title	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
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Arm description:

Subjects received intravenous infusion of M6620 at a dose of 90 mg/m², in combination with irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of M6620 at a dose of 90 mg/m², in combination with irinotecan.

Investigational medicinal product name	Irinotecan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use, Intravenous use

Dosage and administration details:

Subjects received intravenous infusion of irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 in combination with M6620.

Arm title	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
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Arm description:

Subjects with advanced non-small cell lung cancer (NSCLC) received intravenous infusion of M6620 at a dose of 210 mg/m² on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m² on Days 1 and 8 of a 21-day cycle up to 63 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with advanced non-small cell lung cancer (NSCLC) received intravenous infusion of M6620 at a dose of 210 mg/m² on Days 2 and 9 in combination with Gemcitabine.

Investigational medicinal product name	Gemcitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with advanced non-small cell lung cancer (NSCLC) received intravenous infusion of Gemcitabine at a dose of 1000 mg/m² on Days 1 and 8 in combination with M6620.

Arm title	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Arm description:

Subjects with advanced triple negative breast cancer (TNBC) received intravenous infusion of M6620 at a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m² on Day 1 of a 21-day cycle up to 137 weeks.

Arm type	Experimental
Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with advanced triple negative breast cancer (TNBC) received intravenous infusion of M6620 at a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin.

Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with advanced triple negative breast cancer (TNBC) received intravenous infusion of Cisplatin

at a dose of 75 mg/m² on Day 1 in combination with M6620.

Arm title	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Arm description:

Subjects with platinum-resistant advanced small cell lung cancer (SCLC) received intravenous infusion of M6620 at a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m² on Day 1 of a 21-day cycle up to 27 weeks.

Arm type	Experimental
Investigational medicinal product name	Cisplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with platinum-resistant advanced small cell lung cancer (SCLC) received intravenous infusion of Cisplatin at a dose of 75 mg/m² on Day 1 in combination with M6620.

Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with platinum-resistant advanced small cell lung cancer (SCLC) received intravenous infusion of M6620 at a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin.

Arm title	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
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Arm description:

Subjects with platinum-resistant advanced SCLC received intravenous infusion of M6620 at a dose of 90 mg/m² on Days 2 and 9 in combination with carboplatin area under concentration-time curve (AUC) at a dose of 5 milligrams·minute per milliliter on Day 1 of a 21-day cycle up to 27 weeks.

Arm type	Experimental
Investigational medicinal product name	Carboplatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with platinum-resistant advanced SCLC received intravenous infusion of Carboplatin are under concentration-time curve (AUC) at a dose of 5 mg·min/mL on Day 1 in combination with M6620.

Investigational medicinal product name	M6620
Investigational medicinal product code	M6620
Other name	
Pharmaceutical forms	Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects with platinum-resistant advanced SCLC received intravenous infusion of M6620 at a dose of 90 mg/m² on Days 2 and 9 in combination with Carboplatin.

Number of subjects in period 1	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
Started	3	3	4
Completed	3	3	4

Number of subjects in period 1	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
Started	7	6	8
Completed	7	6	8

Number of subjects in period 1	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
Started	3	3	7
Completed	3	3	7

Number of subjects in period 1	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Started	6	6	2
Completed	6	6	2

Number of subjects in period 1	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
Started	1	3	3
Completed	1	3	3

Number of subjects in period 1	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Started	4	10	7
Completed	4	10	7

Number of subjects in period 1	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
Started	3	5	3
Completed	3	5	3

Number of subjects in period 1	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²

Started	38	47	2
Completed	38	47	2

Number of subjects in period 1	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Started	13
Completed	13

Baseline characteristics

Reporting groups

Reporting group title	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at a initial dose of 18 milligrams per square meter (mg/m ²) approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 36 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 60 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 72 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 90 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 140 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 750 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 90 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 and 60	

mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 41 weeks.

Reporting group title	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 120 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 and 60 mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 41 weeks.

Reporting group title	Part B1: M6620 140 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 140mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 60 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 75 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 75 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at a dose of 60 mg/m², in combination with irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.

Reporting group title	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at a dose of 90 mg/m², in combination with irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.

Reporting group title	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
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Reporting group description:

Subjects with advanced non-small cell lung cancer (NSCLC) received intravenous infusion of M6620 at a dose of 210 mg/m² on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m² on Days 1 and 8 of a 21-day cycle up to 63 weeks.

Reporting group title	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects with advanced triple negative breast cancer (TNBC) received intravenous infusion of M6620 at

a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m² on Day 1 of a 21-day cycle up to 137 weeks.

Reporting group title	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects with platinum-resistant advanced small cell lung cancer (SCLC) received intravenous infusion of M6620 at a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m² on Day 1 of a 21-day cycle up to 27 weeks.

Reporting group title	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
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Reporting group description:

Subjects with platinum-resistant advanced SCLC received intravenous infusion of M6620 at a dose of 90 mg/m² on Days 2 and 9 in combination with carboplatin area under concentration-time curve (AUC) at a dose of 5 milligrams·minute per milliliter on Day 1 of a 21-day cycle up to 27 weeks.

Reporting group values	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
Number of subjects	3	3	4
Age Categorical			
Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	2	3
>=65 years	0	1	1
Sex: Female, Male			
Units: subjects			
Female	2	0	1
Male	1	3	3
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	2	4
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	4
Unknown or Not Reported	0	0	0

Reporting group values	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
Number of subjects	7	6	8
Age Categorical			
Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	5	3	6
>=65 years	2	3	2

Sex: Female, Male			
Units: subjects			
Female	4	3	2
Male	3	3	6
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	7	6	8
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	5	8
Unknown or Not Reported	0	1	0

Reporting group values	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
Number of subjects	3	3	7
Age Categorical			
Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	2	3
>=65 years	0	1	4
Sex: Female, Male			
Units: subjects			
Female	2	2	3
Male	1	1	4
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	3	7
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	7
Unknown or Not Reported	0	0	0

Reporting group values	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
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Number of subjects	6	6	2
Age Categorical			
Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	4	2
>=65 years	3	2	0
Sex: Female, Male			
Units: subjects			
Female	3	3	1
Male	3	3	1
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	6	6	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	6	2
Unknown or Not Reported	0	0	0

Reporting group values	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
Number of subjects	1	3	3
Age Categorical			
Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	1	2	0
>=65 years	0	1	3
Sex: Female, Male			
Units: subjects			
Female	1	2	1
Male	0	1	2
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	1	3	2
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	1	3	3

Unknown or Not Reported	0	0	0
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Reporting group values	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Number of subjects	4	10	7
Age Categorical Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	3	4	5
>=65 years	1	6	2
Sex: Female, Male Units: subjects			
Female	1	5	6
Male	3	5	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	3	8	7
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	4	10	7
Unknown or Not Reported	0	0	0

Reporting group values	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
Number of subjects	3	5	3
Age Categorical Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	1	4	2
>=65 years	2	1	1
Sex: Female, Male Units: subjects			
Female	1	3	1
Male	2	2	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0

White	3	3	3
More than one race	0	1	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	5	3
Not Hispanic or Latino	3	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Number of subjects	38	47	2
Age Categorical			
Units: subjects			
<=18 years	0	0	0
Between 18 and 65 years	22	43	2
>=65 years	16	4	0
Sex: Female, Male			
Units: subjects			
Female	18	47	2
Male	20	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	0
White	34	41	2
More than one race	1	0	0
Unknown or Not Reported	2	3	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	3	4	0
Not Hispanic or Latino	32	41	1
Unknown or Not Reported	3	2	1

Reporting group values	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL	Total	
Number of subjects	13	197	
Age Categorical			
Units: subjects			
<=18 years	0	0	
Between 18 and 65 years	6	134	
>=65 years	7	63	
Sex: Female, Male			
Units: subjects			
Female	8	122	
Male	5	75	

Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	5	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	2	6	
White	11	178	
More than one race	0	2	
Unknown or Not Reported	0	6	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	15	
Not Hispanic or Latino	13	175	
Unknown or Not Reported	0	7	

End points

End points reporting groups

Reporting group title	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at a initial dose of 18 milligrams per square meter (mg/m ²) approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 36 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 60 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 72 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 90 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 140 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 750 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 90 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 and 60	

mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 41 weeks.

Reporting group title	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 120 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 and 60 mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 41 weeks.

Reporting group title	Part B1: M6620 140 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1, of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 140mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 40 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 60 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 75 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with 75 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.

Reporting group title	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at a dose of 60 mg/m², in combination with irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.

Reporting group title	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at a dose of 90 mg/m², in combination with irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.

Reporting group title	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
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Reporting group description:

Subjects with advanced non-small cell lung cancer (NSCLC) received intravenous infusion of M6620 at a dose of 210 mg/m² on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m² on Days 1 and 8 of a 21-day cycle up to 63 weeks.

Reporting group title	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects with advanced triple negative breast cancer (TNBC) received intravenous infusion of M6620 at

a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m² on Day 1 of a 21-day cycle up to 137 weeks.

Reporting group title	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
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Reporting group description:

Subjects with platinum-resistant advanced small cell lung cancer (SCLC) received intravenous infusion of M6620 at a dose of 140 mg/m² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m² on Day 1 of a 21-day cycle up to 27 weeks.

Reporting group title	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
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Reporting group description:

Subjects with platinum-resistant advanced SCLC received intravenous infusion of M6620 at a dose of 90 mg/m² on Days 2 and 9 in combination with carboplatin area under concentration-time curve (AUC) at a dose of 5 milligrams·minute per milliliter on Day 1 of a 21-day cycle up to 27 weeks.

Subject analysis set title	Part A1: All Subjects
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Subjects who received M6620 at a dose of 18, 36, 60, 72, 90, 140 or 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875, 500, 750 or 1000 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Subject analysis set title	Part A2: All Subjects
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Subjects who received M6620 at a dose of 90 or 120 mg/m² in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 and 60 mg/m² of Cisplatin on Day 1 of a 21-day cycle up to 41 weeks.

Subject analysis set title	Parts B1: All Subjects
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Subjects who received intravenous infusion of M6620 at dose of 140, 90 or 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin at a dose 40, 60 or 75 mg/m² on Day 1 of a 21-day cycle up to 74 weeks.

Subject analysis set title	Part B2: All Subjects
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Subjects who received intravenous infusion of M6620 at a dose of 60 or 90 mg/m² in combination with irinotecan at a dose of 180 mg/m² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.

Subject analysis set title	Part A1: M6620 120 mg/m ² and Gemcitabine
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Subject analysis set type	Full analysis
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Subject analysis set description:

Subjects who received intravenous infusion of M6620 at escalated dose of 120 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500, 750, 875 or 1000 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Subject analysis set title	Part A1: M6620 210 mg/m ² and Gemcitabine
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Subject analysis set type	Full analysis
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Subject analysis set description:

Subjects who received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 750, 875 or 1000 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Subject analysis set title	Part B1: M6620 140 mg/m ² and Cisplatin
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Subject analysis set type	Full analysis
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Subject analysis set description:

Subjects who received intravenous infusion of M6620 at dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin at a dose of 40 or 75 mg/m² on Day 1 of a 21-day cycle up to 74 weeks.

Subject analysis set title	Part B1: M6620 210 mg/m ² and Cisplatin
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Subject analysis set type	Full analysis
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Subject analysis set description:

Subjects who received intravenous infusion of M6620 at dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin at a dose of 40, 60 or 75 mg/m² on Day 1 of a 21-day cycle up to 74 weeks.

Primary: Parts A1, A2, B1: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs)

End point title	Parts A1, A2, B1: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs) ^{[1][2]}
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End point description:

Adverse event (AE) was defined as any untoward medical occurrence in a subject, which does not necessarily have causal relationship with treatment. A serious AE was defined as an AE that resulted in any of the following outcomes: death; life threatening; persistent/significant disability/incapacity; initial or prolonged inpatient hospitalization; congenital anomaly/birth defect or was otherwise considered medically important. TEAEs were those events with onset dates occurring during the on-treatment period for the first time, or if the worsening of an event was during the on-treatment period. TEAEs included both serious TEAEs and non-serious TEAEs. Safety set included all subjects who received at least 1 dose of study drug.

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 4.6 years

Notes:

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

Justification: Only descriptive summary statistics 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: In this endpoint, we have reported data for Part A1, Part A2 and Part B1 arms only. For Part B2, Part C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	7
Units: subjects	3	3	4	6

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	3	3
Units: subjects	6	8	3	3

End point values	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	6	2
Units: subjects	7	6	6	2

End point values	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	3	4
Units: subjects	1	3	3	3

End point values	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	7	3	
Units: subjects	10	7	3	

Statistical analyses

No statistical analyses for this end point

Primary: Parts A1, A2, B1: Number of Subjects with Clinically Significant Changes From Baseline in Laboratory Parameters

End point title	Parts A1, A2, B1: Number of Subjects with Clinically Significant Changes From Baseline in Laboratory Parameters ^{[3][4]}
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End point description:

Laboratory investigation included hematology, biochemistry, urinalysis and coagulation. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in laboratory parameters were reported. Safety set included all subjects who received at least 1 dose of study drug.

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 4.6 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: Only descriptive summary statistics 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: In this endpoint, we have reported data for Part A1, Part A2 and Part B1 arms only. For Part B2, Part C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	7
Units: subjects	0	0	0	0

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	3	3
Units: subjects	0	0	0	0

End point values	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	6	2
Units: subjects	0	0	0	0

End point values	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	3	4
Units: subjects	0	0	0	0

End point values	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	7	3	
Units: subjects	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Parts A1, A2, B1: Number of Subjects with Clinically Significant Changes From Baseline in Vital Signs

End point title	Parts A1, A2, B1: Number of Subjects with Clinically Significant Changes From Baseline in Vital Signs ^[5] ^[6]
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End point description:

Vital signs included body temperature, systolic and diastolic blood pressure, pulse rate and respiratory

rate. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in vital signs were reported. Safety set included all subjects who received at least 1 dose of study drug.

End point type	Primary
End point timeframe:	
Time from first dose of study treatment up to 4.6 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: Only descriptive summary statistics 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: In this endpoint, we have reported data for Part A1, Part A2 and Part B1 arms only. For Part B2, Part C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	7
Units: subjects	0	0	0	0

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	3	3
Units: subjects	0	0	0	0

End point values	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	6	2
Units: subjects	0	0	0	0

End point values	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	3	4
Units: subjects	0	0	0	0

End point values	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	7	3	
Units: subjects	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Parts A1, A2, B1: Number of Subjects with Clinically Significant Changes From Baseline in 12-Lead Electrocardiograms (ECGs) Findings

End point title	Parts A1, A2, B1: Number of Subjects with Clinically Significant Changes From Baseline in 12-Lead Electrocardiograms (ECGs) Findings ^{[7][8]}
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End point description:

12-lead ECG recordings included rhythm, heart rate (as measured by RR interval), PR interval, QRS duration, and QT interval. 12-lead ECG recordings were obtained after the subjects have rested for at least 5 minutes in supine position. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in 12-lead ECG findings were reported. Safety set included all subjects who received at least 1 dose of study drug.

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 4.6 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[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: In this endpoint, we have reported data for Part A1, Part A2 and Part B1 arms only. For Part B2, Part C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	7
Units: subjects	0	0	0	0

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	8	3	3
Units: subjects	0	0	0	0

End point values	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	6	6	2
Units: subjects	0	0	0	0

End point values	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	3	4
Units: subjects	0	0	0	0

End point values	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	7	3	
Units: subjects	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Part B2: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs)

End point title	Part B2: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs) ^{[9][10]}
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End point description:

Adverse event (AE) was defined as any untoward medical occurrence in a subject, which does not necessarily have causal relationship with treatment. A serious AE was defined as an AE that resulted in any of the following outcomes: death; life threatening; persistent/significant disability/incapacity; initial or prolonged inpatient hospitalization; congenital anomaly/birth defect or was otherwise considered medically important. TEAEs were those events with onset dates occurring during the on-treatment period for the first time, or if the worsening of an event was during the on-treatment period. TEAEs included both serious TEAEs and non-serious TEAEs. Safety Analysis Set (SAF) included all screening analysis set subjects who received at least 1 administration of study drug (irinotecan or M6620).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 1.6 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: subjects	5	3		

Statistical analyses

No statistical analyses for this end point

Primary: Part B2: Number of Subjects with Clinically Significant Changes from Baseline in Laboratory Parameters

End point title	Part B2: Number of Subjects with Clinically Significant Changes from Baseline in Laboratory Parameters ^{[11][12]}
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End point description:

Laboratory investigation included hematology, biochemistry, urinalysis and coagulation. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in laboratory parameters were reported. SAF included all screening analysis set subjects who received at least 1 administration of study drug (irinotecan or M6620).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 1.6 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part B2: Number of Subjects with Clinically Significant Changes from Baseline in Vital Signs

End point title	Part B2: Number of Subjects with Clinically Significant Changes from Baseline in Vital Signs ^{[13][14]}
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End point description:

Vital signs included body temperature, systolic and diastolic blood pressure, pulse rate and respiratory rate. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in vital signs were reported. SAF included all screening analysis set subjects who received at least 1 administration of study drug (irinotecan or M6620).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 1.6 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Part B2: Number of Subjects with Clinically Significant Changes from Baseline in 12-Lead Electrocardiograms (ECGs) Findings

End point title	Part B2: Number of Subjects with Clinically Significant Changes from Baseline in 12-Lead Electrocardiograms (ECGs) Findings ^{[15][16]}
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End point description:

12-lead ECG recordings included rhythm, heart rate (as measured by RR interval), PR interval, QRS duration, and QT interval. 12-lead ECG recordings were obtained after the subjects have rested for at least 5 minutes in supine position. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in 12-lead ECG findings were reported. SAF included all screening analysis set subjects who received at least 1 administration of study drug (irinotecan or M6620).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 1.6 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

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

Justification: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	3		
Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Parts C1, C2, C3: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs)

End point title	Parts C1, C2, C3: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs) ^{[17][18]}
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End point description:

Adverse event (AE) was defined as any untoward medical occurrence in a subject, which does not necessarily have causal relationship with treatment. A serious AE was defined as an AE that resulted in any of the following outcomes: death; life threatening; persistent/significant disability/incapacity; initial or prolonged inpatient hospitalization; congenital anomaly/birth defect or was otherwise considered medically important. TEAEs were those events with onset dates occurring during the on-treatment period for the first time, or if the worsening of an event was during the on-treatment period. TEAEs included both serious TEAEs and non-serious TEAEs. SAF: all enrolled subjects (irrespective of biomarker status) who received at least 1 dose of study drug (M6620, gemcitabine, cisplatin, or carboplatin; actual amount > 0 mg and/or the duration of infusion > 0 minutes).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 4.3 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[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: In this endpoint, we have reported data for Part C1, C2 and C3 arms only. For Parts A1, A2, B1 and B2 arms we have created separate endpoints due to change in the time frame.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	47	2	13

Units: subjects	38	47	2	13
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Statistical analyses

No statistical analyses for this end point

Primary: Parts C1, C2, C3: Number of Subjects with Clinically Significant Changes from Baseline in Laboratory Parameters

End point title	Parts C1, C2, C3: Number of Subjects with Clinically Significant Changes from Baseline in Laboratory Parameters ^{[19][20]}
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End point description:

Laboratory investigation included hematology, biochemistry, urinalysis and coagulation. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in laboratory parameters were reported. SAF: all enrolled subjects (irrespective of biomarker status) who received at least 1 dose of study drug (M6620, gemcitabine, cisplatin, or carboplatin; actual amount > 0 mg and/or the duration of infusion > 0 minutes).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 4.3 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints due to change in the time frame.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	47	2	13
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Parts C1, C2, C3: Number of Subjects with Clinically Significant Changes from Baseline in Vital Signs

End point title	Parts C1, C2, C3: Number of Subjects with Clinically Significant Changes from Baseline in Vital Signs ^{[21][22]}
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End point description:

Vital signs included body temperature, systolic and diastolic blood pressure, pulse rate and respiratory rate. Clinical significance was determined by the investigator. The number of subjects with clinically

significant changes from baseline in vital signs were reported. SAF: all enrolled subjects (irrespective of biomarker status) who received at least 1 dose of study drug (M6620, gemcitabine, cisplatin, or carboplatin; actual amount > 0 mg and/or the duration of infusion > 0 minutes).

End point type	Primary
End point timeframe:	
Time from first dose of study treatment up to 4.3 years	

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[22] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints due to change in the time frame.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	47	2	13
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Parts C1, C2 and C3: Number of Subjects with Clinically Significant Changes from Baseline in 12-Lead Electrocardiograms (ECGs) Findings

End point title	Parts C1, C2 and C3: Number of Subjects with Clinically Significant Changes from Baseline in 12-Lead Electrocardiograms (ECGs) Findings ^{[23][24]}
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End point description:

12-lead ECG recordings included rhythm, heart rate (as measured by RR interval), PR interval, QRS duration, and QT interval. 12-lead ECG recordings were obtained after the subjects have rested for at least 5 minutes in supine position. Clinical significance was determined by the investigator. The number of subjects with clinically significant changes from baseline in 12-lead ECG findings were reported. SAF: all enrolled subjects (irrespective of biomarker status) who received at least 1 dose of study drug (M6620, gemcitabine, cisplatin, or carboplatin; actual amount > 0 mg and/or the duration of infusion > 0 minutes).

End point type	Primary
End point timeframe:	
Time from first dose of study treatment up to 4.3 years	

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[24] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints due to change in the time frame.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	47	2	13
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Parts C1 and C3: Percentage of Subjects with Objective Response (OR)

End point title	Parts C1 and C3: Percentage of Subjects with Objective Response (OR) ^{[25][26]}
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End point description:

OR was defined as the percentage of subjects who had achieved partial response (PR) or complete response (CR) as the best overall response according to according to Response Evaluation Criteria In Solid Tumors version 1.1 (RECIST v1.1). CR: Disappearance of all evidence of target and non-target lesions. PR: At least 30% reduction from baseline in the sum of the longest diameter (SLD) of all lesions. Modified Full Analysis Set (mFAS): all enrolled subjects who satisfy both of following conditions:1) Received at least 1 dose of study drug (M6620, gemcitabine, cisplatin/carboplatin with the actual amount greater than [$>$] 0 mg and/the duration of infusion $>$ 0 minutes; 2) Had a Baseline scan of disease assessment (Computed tomography [CT]/Magnetic resonance imaging [MRI]) with a measurable target lesion (sum of diameters of all target lesions $>$ 0 millimeter [mm]).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 4.3 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[26] - 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: In this endpoint, we have reported data for Parts C1 and C3 arms only. For Part A1, A2, B1, B2 and C2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	2	13	
Units: percentage of subjects				
number (confidence interval 90%)	10.5 (3.7 to 22.5)	0.0 (0.0 to 77.6)	0.0 (0.0 to 20.6)	

Statistical analyses

Primary: Part C2: Percentage of Subjects with Objective Response (OR) in Part C2 (TNBC) Who are Basaloid Subtype and BRCA1/BRCA2 Germline wild-type

End point title	Part C2: Percentage of Subjects with Objective Response (OR) in Part C2 (TNBC) Who are Basaloid Subtype and BRCA1/BRCA2 Germline wild-type ^[27] ^[28]
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End point description:

OR was defined as the percentage of subjects who had achieved partial response (PR) or complete response (CR) as the best overall response according to Response Evaluation Criteria In Solid Tumors version 1.1 (RECIST v1.1). CR: Disappearance of all evidence of target and non-target lesions. PR: At least 30% reduction from baseline in the sum of the longest diameter (SLD) of all lesions. Modified Full Analysis Set (mFAS): all enrolled subjects who satisfy both of following conditions: 1) Received at least 1 dose of study drug (M6620, gemcitabine, cisplatin/carboplatin with the actual amount greater than [$>$] 0 mg and/the duration of infusion $>$ 0 minutes; 2) Had a Baseline scan of disease assessment (Computed tomography [CT]/Magnetic resonance imaging [MRI]) with a measurable target lesion (sum of diameters of all target lesions $>$ 0 millimeter [mm]).

End point type	Primary
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End point timeframe:

Time from first dose of study treatment up to 4.3 years

Notes:

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

Justification: Only descriptive summary statistics was planned for this endpoint.

[28] - 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: In this endpoint, the data was planned to be reported for subjects with Basaloid subtype (BRCA1/BRCA2) in Part B2 only.

End point values	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percentage of subjects				
number (confidence interval 90%)	22.6 (11.1 to 38.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A1 and A2: Maximum Tolerated Dose (MTD) of M6620

End point title	Parts A1 and A2: Maximum Tolerated Dose (MTD) of M6620
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End point description:

Part A1: MTD of M6620 with gemcitabine was defined as the highest dose of M6620 tolerated in combination with a gemcitabine. Part A2: MTD of M6620 was defined as the highest dose of M6620 tolerated in combination with a cisplatin and gemcitabine. Dose limiting toxicity (DLT) evaluable set was defined as all subjects enrolled in Part A or Part B1 who either had a DLT before Day 21 in Cycle 1; or received all doses of gemcitabine and/or cisplatin, as applicable, and all doses of M6620 during Cycle.

End point type	Secondary
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End point timeframe:

Up to Cycle 1 Day 21 (each cycle is 21 days)

End point values	Part A1: All Subjects	Part A2: All Subjects		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	50	8		
Units: mg/m ²				
number (not applicable)	210	90		

Statistical analyses

No statistical analyses for this end point

Secondary: Part A1: Maximum Observed Plasma Concentration (C_{max}) of M6620

End point title	Part A1: Maximum Observed Plasma Concentration (C _{max}) of M6620 ^[29]
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End point description:

C_{max} was obtained directly from the concentration versus time curve. Full Analysis Set (FAS) included all subjects who had baseline scan and received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to progression disease [PD] or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[29] - 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: In this endpoint, we have reported data for Part A1 arms only. For Parts A2, B1, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 120 mg/m ² and Gemcitabine	Part A1: M6620 210 mg/m ² and Gemcitabine	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	2	16	
Units: nanogram per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	571 (± 34)	486 (± 28)	899 (± 41)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A1: Area Under the Plasma Concentration-Time Curve From Time 0 to Infinity (AUC_{0-inf}) of M6620

End point title	Part A1: Area Under the Plasma Concentration-Time Curve
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End point description:

AUC0-inf was calculated by combining AUC0-t and AUCextra. AUC extra represents an extrapolated value obtained by C_{last}/λ_z , where C_{last} is the calculated plasma concentration at the last sampling time point at which the measured plasma concentration is at or above the Lower Limit of quantification (LLOQ) and λ_z is the apparent terminal rate constant determined by log-linear regression analysis of the measured plasma concentrations of the terminal log-linear phase. FAS included all subject who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to progression disease [PD] or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[30] - 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: In this endpoint, we have reported data for Part A1 arms only. For Parts A2, B1, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 120 mg/m ² and Gemcitabine	Part A1: M6620 210 mg/m ² and Gemcitabine	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	2	16	
Units: nanogram*hour per milliliter (ng*hr/mL)				
geometric mean (geometric coefficient of variation)	3100 (± 39)	4160 (± 3.5)	6690 (± 31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A1: Apparent Volume of Distribution at Steady-state (Vss) of M6620

End point title	Part A1: Apparent Volume of Distribution at Steady-state (Vss) of M6620 ^[31]
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End point description:

Vss was defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug. Steady state volume of distribution (Vss) was the apparent volume of distribution at steady-state. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to progression disease [PD] or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[31] - 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: In this endpoint, we have reported data for Part A1 arms only. For Parts A2, B1, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 120 mg/m ² and Gemcitabine	Part A1: M6620 210 mg/m ² and Gemcitabine	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	2	16	
Units: liters				
geometric mean (geometric coefficient of variation)	983 (± 35)	1240 (± 14)	1250 (± 22)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A1: Apparent Total Body Clearance (CL) of M6620

End point title	Part A1: Apparent Total Body Clearance (CL) of M6620 ^[32]
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End point description:

CL was a measure of the rate at which M6620 was metabolized or eliminated by normal biological processes. Clearance obtained after oral dose was influenced by the fraction of the dose absorbed. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[32] - 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: In this endpoint, we have reported data for Part A1 arms only. For Parts A2, B1, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 120 mg/m ² and Gemcitabine	Part A1: M6620 210 mg/m ² and Gemcitabine	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	2	16	
Units: liter per hour				
geometric mean (geometric coefficient of variation)	64.2 (± 45)	55.5 (± 1)	62.3 (± 31)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part A1: Apparent Terminal Half-Life (t_{1/2}) of M6620

End point title	Part A1: Apparent Terminal Half-Life (t _{1/2}) of M6620 ^[33]
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End point description:

Apparent terminal half-life was defined as the time required for the plasma concentration of drug to decrease 50 percent in the final stage of its elimination. FAS included all subjects who had baseline

scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

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

Justification: In this endpoint, we have reported data for Part A1 arms only. For Parts A2, B1, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 120 mg/m ² and Gemcitabine	Part A1: M6620 210 mg/m ² and Gemcitabine	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	2	16	
Units: hours				
geometric mean (geometric coefficient of variation)	14.2 (± 27)	17.6 (± 14)	17.3 (± 24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Parts A1, A2 and B1: Percentage of Subjects with Objective Tumor Response (OR) as Evaluated by Response Criteria Evaluation in Solid Tumors (RECIST) 1.1

End point title	Parts A1, A2 and B1: Percentage of Subjects with Objective Tumor Response (OR) as Evaluated by Response Criteria Evaluation in Solid Tumors (RECIST) 1.1 ^[34]
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End point description:

Objective tumor response was defined as having a complete response (CR) or a partial response (PR). Complete Response (CR): Disappearance of all target lesions. Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death). Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint. Here, '99999' signifies that data is not available as none of the subjects showed CR or PR at specified time point.

End point type	Secondary
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End point timeframe:

Time from first dose of study treatment up to 4.6 years

Notes:

[34] - 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: In this endpoint, we have reported data for Part A1, Part A2 and Part B1 arms only. For Part B2, Part C1, C2 and C3 arms we have created separate endpoints due to change in the time frame.

End point values	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	7
Units: percentage of subjects				
number (confidence interval 90%)	99999 (99999 to 99999)	33.3 (1.7 to 86.5)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	3	3
Units: percentage of subjects				
number (confidence interval 90%)	99999 (99999 to 99999)	28.6 (5.3 to 65.9)	99999 (99999 to 99999)	33.3 (1.7 to 86.5)

End point values	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	1
Units: percentage of subjects				
number (confidence interval 90%)	99999 (99999 to 99999)	99999 (99999 to 99999)	16.7 (0.9 to 58.2)	99999 (99999 to 99999)

End point values	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	9
Units: percentage of subjects				
number (confidence interval 90%)	99999 (99999 to 99999)	25.0 (1.3 to 75.1)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	3		
Units: percentage of subjects				

number (confidence interval 90%)	75.0 (24.9 to 98.7)	99999 (99999 to 99999)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Part B1: Maximum Tolerated Dose (MTD) of M6620

End point title	Part B1: Maximum Tolerated Dose (MTD) of M6620
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End point description:

M6620 MTD was defined as the highest dose of M6620 tolerated in combination with a cisplatin. DLT evaluable set was defined as all subjects enrolled in Part A or Part B1 who either had a DLT before Day 21 in Cycle 1; or received all doses of gemcitabine and/or cisplatin, as applicable, and all doses of M6620 during Cycle.

End point type	Secondary
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End point timeframe:

Up to Cycle 1 Day 21 (each cycle is 21 days)

End point values	Parts B1: All Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	31			
Units: mg/m ²				
number (not applicable)	140			

Statistical analyses

No statistical analyses for this end point

Secondary: Part B2: Maximum Tolerated Dose (MTD) of M6620

End point title	Part B2: Maximum Tolerated Dose (MTD) of M6620
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End point description:

The MTD for M6620 in combination with irinotecan was defined as the highest dose for a given schedule at which there were no more than 1 of 6 subjects with DLT. DLT Evaluable Set: all SAF subjects who either experienced a DLT before the end of Cycle 1 and received any amount of M6620 or received at least 80% of the cumulative planned dose of irinotecan and at least 80% of the cumulative planned dose of M6620 during Cycle 1 and completed Cycle 1, i.e., had a study visit on Day 28 or later

End point type	Secondary
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End point timeframe:

Up to Cycle 1 Day 28 (each cycle is of 28 days)

End point values	Part B2: All Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	0 ^[35]			
Units: mg/m ²				
number (not applicable)				

Notes:

[35] - MTD was not determined as Part B2 was discontinued after observing toxicities at first dose level.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B1: Maximum Observed Plasma Concentration (Cmax) of M6620

End point title	Part B1: Maximum Observed Plasma Concentration (Cmax) of M6620 ^[36]
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End point description:

Cmax was obtained directly from the concentration versus time curve. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after EOI on Cycle 1 Day 2 (each cycle is 21 days)

Notes:

[36] - 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: In this endpoint, we have reported data for Part B1 arms only. For Parts A1, A2, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² and Cisplatin	Part B1: M6620 210 mg/m ² and Cisplatin	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	8	17	
Units: nanogram per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	458 (± 13)	854 (± 63)	1230 (± 43)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B1: Area Under the Plasma Concentration-Time Curve From Time 0 to Infinity (AUC0-inf) of M6620

End point title	Part B1: Area Under the Plasma Concentration-Time Curve From Time 0 to Infinity (AUC0-inf) of M6620 ^[37]
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End point description:

AUC0-inf was calculated by combining AUC0-t and AUCextra. AUC extra represents an extrapolated value obtained by $\text{Clas}t / \lambda z$, where $\text{Clas}t$ is the calculated plasma concentration at the last sampling time point at which the measured plasma concentration is at or above the Lower Limit of quantification (LLOQ) and λz is the apparent terminal rate constant determined by log-linear

regression analysis of the measured plasma concentrations of the terminal log-linear phase. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death).

End point type	Secondary
End point timeframe:	
Pre-infusion, 0.5, 1, 2, 3 and 7 hours after EOI on Cycle 1 Day 2 (each cycle is 21 days)	

Notes:

[37] - 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: In this endpoint, we have reported data for Part B1 arms only. For Parts A1, A2, B2, C1, C2 and C3 arms we have created separate endpoint.

End point values	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² and Cisplatin	Part B1: M6620 210 mg/m ² and Cisplatin	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	8	17	
Units: nanogram*hour per milliliter (ng*hr/mL)				
geometric mean (geometric coefficient of variation)	2820 (± 15)	4870 (± 28)	6740 (± 32)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B1: Apparent Volume of Distribution at Steady-state (Vss) of M6620

End point title	Part B1: Apparent Volume of Distribution at Steady-state (Vss) of M6620 ^[38]
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End point description:

Vss was defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug. Steady state volume of distribution (Vss) was the apparent volume of distribution at steady-state. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death).

End point type	Secondary
End point timeframe:	
Pre-infusion, 0.5, 1, 2, 3 and 7 hours after EOI on Cycle 1 Day 2 (each cycle is 21 days)	

Notes:

[38] - 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: In this endpoint, we have reported data for Part B1 arms only. For Parts A1, A2, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² and Cisplatin	Part B1: M6620 210 mg/m ² and Cisplatin	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	8	17	
Units: liters				

geometric mean (geometric coefficient of variation)	1260 (± 38)	1060 (± 36)	1270 (± 28)	
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Statistical analyses

No statistical analyses for this end point

Secondary: Part B1: Apparent Total Body Clearance (CL) of M6620

End point title	Part B1: Apparent Total Body Clearance (CL) of M6620 ^[39]
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End point description:

CL was a measure of the rate at which M6620 was metabolized or eliminated by normal biological processes. Clearance obtained after oral dose was influenced by the fraction of the dose absorbed. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after EOI on Cycle 1 Day 2 (each cycle is 21 days)

Notes:

[39] - 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: In this endpoint, we have reported data for Part B1 arms only. For Parts A1, A2, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² and Cisplatin	Part B1: M6620 210 mg/m ² and Cisplatin	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	8	17	
Units: liters				
geometric mean (geometric coefficient of variation)	61.1 (± 20)	54.7 (± 31)	62.6 (± 32)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B1: Apparent Terminal Half-Life (t_{1/2}) of M6620

End point title	Part B1: Apparent Terminal Half-Life (t _{1/2}) of M6620 ^[40]
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End point description:

Apparent terminal half-life was defined as the time required for the plasma concentration of drug to decrease 50 percent in the final stage of its elimination. FAS included all subjects who had baseline scan, received at least 1 dose of study drug and had at least once post-baseline disease assessment (including staging CT scan or nonstaging CT scan indicating disease progression, end of treatment due to PD or death).

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after EOI on Cycle 1 Day 2 (each cycle is 21 days)

Notes:

[40] - 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: In this endpoint, we have reported data for Part B1 arms only. For Parts A1, A2, B2, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² and Cisplatin	Part B1: M6620 210 mg/m ² and Cisplatin	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	2	8	17	
Units: hours				
geometric mean (geometric coefficient of variation)	17.0 (± 26)	17.5 (± 34)	17.3 (± 17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part B2: Maximum Observed Plasma Concentration (Cmax) of M6620

End point title	Part B2: Maximum Observed Plasma Concentration (Cmax) of M6620 ^[41]
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End point description:

Cmax was obtained directly from the concentration versus time curve. Pharmacokinetic Analysis Set (PAS) included all SAF subjects who received at least 1 administration of study drug (irinotecan or M6620) and provided at least 1 measurable postdose concentration of M6620 or irinotecan or its metabolites.

End point type	Secondary
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End point timeframe:

Cycle 1 Days 1 through 3: pre-infusion, and 1, 2, 3, 7, 23 and 47 hours after EOI; Cycle 1 Day 15 and Cycle 2 Day 1 at pre-infusion, and EOI to 2 hours after EOI (each cycle is of 28 days)

Notes:

[41] - 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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[42]	0 ^[43]		
Units: ng/mL				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[42] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

[43] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

Statistical analyses

Secondary: Part B2: Area Under the Plasma Concentration-Time Curve From Time 0 to Infinity (AUC0-inf) of M6620

End point title	Part B2: Area Under the Plasma Concentration-Time Curve From Time 0 to Infinity (AUC0-inf) of M6620 ^[44]
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End point description:

AUC0-inf was calculated by combining AUC0-t and AUCextra. AUC extra represents an extrapolated value obtained by C_{last}/λ_z , where C_{last} is the calculated plasma concentration at the last sampling time point at which the measured plasma concentration is at or above the Lower Limit of quantification (LLOQ) and λ_z is the apparent terminal rate constant determined by log-linear regression analysis of the measured plasma concentrations of the terminal log-linear phase. PAS included all SAF subjects who received at least 1 administration of study drug (irinotecan or M6620) and provided at least 1 measurable postdose concentration of M6620 or irinotecan or its metabolites.

End point type	Secondary
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End point timeframe:

Cycle 1 Days 1 through 3: pre-infusion, and 1, 2, 3, 7, 23 and 47 hours after EOI; Cycle 1 Day 15 and Cycle 2 Day 1 at pre-infusion, and EOI to 2 hours after EOI (each cycle is of 28 days)

Notes:

[44] - 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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[45]	0 ^[46]		
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[45] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

[46] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B2: Volume of Distribution at Steady-state (Vss) of M6620

End point title	Part B2: Volume of Distribution at Steady-state (Vss) of
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End point description:

Vss was defined as the theoretical volume in which the total amount of drug would need to be uniformly distributed to produce the desired blood concentration of a drug. Steady state volume of distribution (Vss) was the apparent volume of distribution at steady-state. PAS included all SAF subjects who received at least 1 administration of study drug (irinotecan or M6620) and provided at least 1 measurable postdose concentration of M6620 or irinotecan or its metabolites

End point type	Secondary
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End point timeframe:

Cycle 1 Days 1 through 3: pre-infusion, and 1, 2, 3, 7, 23 and 47 hours after EOI; Cycle 1 Day 15 and Cycle 2 Day 1 at pre-infusion, and EOI to 2 hours after EOI (each cycle is of 28 days)

Notes:

[47] - 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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[48]	0 ^[49]		
Units: liters				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[48] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

[49] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B2: Apparent Total Body Clearance (CL) of M6620

End point title	Part B2: Apparent Total Body Clearance (CL) of M6620 ^[50]
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End point description:

CL was a measure of the rate at which M6620 was metabolized or eliminated by normal biological processes. Clearance obtained after oral dose was influenced by the fraction of the dose absorbed. PAS included all SAF subjects who received at least 1 administration of study drug (irinotecan or M6620) and provided at least 1 measurable postdose concentration of M6620 or irinotecan or its metabolites.

End point type	Secondary
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End point timeframe:

Cycle 1 Days 1 through 3: pre-infusion, and 1, 2, 3, 7, 23 and 47 hours after EOI; Cycle 1 Day 15 and Cycle 2 Day 1 at pre-infusion, and EOI to 2 hours after EOI (each cycle is of 28 days)

Notes:

[50] - 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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[51]	0 ^[52]		
Units: liter per hour				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[51] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

[52] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

Statistical analyses

Secondary: Part B2: Apparent Terminal Half-Life (t_{1/2}) of M6620

End point title	Part B2: Apparent Terminal Half-Life (t _{1/2}) of M6620 ^[53]
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End point description:

Apparent terminal half-life was defined as the time required for the plasma concentration of drug to decrease 50 percent in the final stage of its elimination. PAS included all SAF subjects who received at least 1 administration of study drug (irinotecan or M6620) and provided at least 1 measurable postdose concentration of M6620 or irinotecan or its metabolites.

End point type	Secondary
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End point timeframe:

Cycle 1 Days 1 through 3: pre-infusion, and 1, 2, 3, 7, 23 and 47 hours after EOI; Cycle 1 Day 15 and Cycle 2 Day 1 at pre-infusion, and EOI to 2 hours after EOI (each cycle is of 28 days)

Notes:

[53] - 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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[54]	0 ^[55]		
Units: hours				
geometric mean (geometric coefficient of variation)	()	()		

Notes:

[54] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

[55] - As per revised planned analysis, pharmacokinetic parameters for Part B2 was not assessed.

Statistical analyses

No statistical analyses for this end point

Secondary: Part B2: Percentage of Subjects with Objective Tumor Response (OR) as Evaluated by Response Criteria Evaluation in Solid Tumors (RECIST) 1.1

End point title	Part B2: Percentage of Subjects with Objective Tumor Response (OR) as Evaluated by Response Criteria Evaluation in Solid Tumors (RECIST) 1.1 ^[56]
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End point description:

OR was defined as the percentage of subjects who had achieved partial response (PR) or complete response (CR) as the best overall response according to Response Evaluation Criteria In Solid Tumors version 1.1 (RECIST v1.1). CR: Disappearance of all evidence of target and non-target lesions. PR: At least 30% reduction from baseline in the sum of the longest diameter (SLD) of all lesions. FAS included all SAF subjects who had a baseline scan and at least 1 disease assessment on treatment.

End point type	Secondary
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End point timeframe:

Time from first dose of study treatment up to 1.6 years

Notes:

[56] - 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: In this endpoint, we have reported data for Part B2 arms only. For Parts A1, A2, B1, C1, C2 and C3 arms we have created separate endpoints.

End point values	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[57]	0 ^[58]		
Units: percentage of subjects				
number (confidence interval 90%)	(to)	(to)		

Notes:

[57] - OR was not calculated as Part B2 was discontinued after observing toxicities at first dose level.

[58] - OR was not calculated as Part B2 was discontinued after observing toxicities at first dose level.

Statistical analyses

No statistical analyses for this end point

Secondary: Part C2: Percentage of Subjects with Objective Response (OR)

End point title	Part C2: Percentage of Subjects with Objective Response
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End point description:

OR was defined as the percentage of subjects who had achieved partial response (PR) or complete response (CR) as the best overall response according to according to Response Evaluation Criteria In Solid Tumors version 1.1 (RECIST v1.1). CR: Disappearance of all evidence of target and non-target lesions. PR: At least 30% reduction from baseline in the sum of the longest diameter (SLD) of all lesions. mFAS: all enrolled subjects who satisfy both of following conditions: 1) Received at least 1 dose of study drug (M6620, gemcitabine, cisplatin/carboplatin with the actual amount greater than [$>$] 0 mg and/the duration of infusion $>$ 0 minutes; 2) Had a Baseline scan of disease assessment (Computed tomography [CT]/Magnetic resonance imaging [MRI]) with a measurable target lesion (sum of diameters of all target lesions $>$ 0 millimeter [mm]).

End point type	Secondary
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End point timeframe:

Time from first dose of study treatment up to 4.3 years

Notes:

[59] - 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: In this endpoint, the data was planned to be reported for Part C2 arm only.

End point values	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²			
Subject group type	Reporting group			
Number of subjects analysed	47			
Units: percentage of subjects				
number (confidence interval 90%)	23.4 (13.7 to 35.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2, C3: Progression Free Survival (PFS) According to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1)

End point title	Parts C1, C2, C3: Progression Free Survival (PFS) According to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) ^[60]
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End point description:

PFS according to RECIST v1.1 was defined as the time from the date of the first dose of a study drug to the date of the first documentation of progressive disease (PD) or death due to any cause, whichever occurs first. PD was defined as at least a 20 percent (%) increase in the SLD, taking as reference the smallest SLD recorded from baseline or the appearance of 1 or more new lesions. mFAS: all enrolled subjects who satisfy both of following conditions: 1) Received at least 1 dose of study drug (M6620, gemcitabine, cisplatin/carboplatin with the actual amount greater than [$>$] 0 mg and/the duration of infusion $>$ 0 minutes; 2) Had a Baseline scan of disease assessment (Computed tomography [CT]/Magnetic resonance imaging [MRI]) with a measurable target lesion (sum of diameters of all target lesions $>$ 0 millimeter [mm]).

End point type	Secondary
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End point timeframe:

Time from first dose of study treatment to 4.3 years

Notes:

[60] - 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: In this endpoint, the data was planned to be reported for Parts C1, C2 and C3 arms only .

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	47	2	13
Units: months				
median (confidence interval 90%)	4.0 (3.2 to 5.0)	4.0 (2.8 to 6.0)	3.3 (1.2 to 5.3)	1.9 (1.4 to 2.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2, C3: Duration of Response (DoR)

End point title	Parts C1, C2, C3: Duration of Response (DoR) ^[61]
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End point description:

DoR was calculated only for those subjects who achieved a CR or PR and was measured from the time the response criteria were first met for CR/PR (whichever was recorded first) until the first date that recurrent or PD was objectively documented. FAS: all enrolled subjects who satisfy both of following conditions: 1) Received at least 1 dose of study drug (M6620, gemcitabine, cisplatin/carboplatin with the actual amount greater than [$>$] 0 mg and/the duration of infusion $>$ 0 minutes; 2) Had a Baseline scan of disease assessment (Computed tomography [CT]/Magnetic resonance imaging [MRI]) with a measurable target lesion (sum of diameters of all target lesions $>$ 0 millimeter [mm]). As there were no responders (CR or PR) in Part C3 (mFAS), the analysis of DoR is presented for Parts C1 and C2 only. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint .

End point type	Secondary
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End point timeframe:

Time from first dose of study treatment to 4.3 years

Notes:

[61] - 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: In this endpoint, the data was planned to be reported for Parts C1, C2 and C3 arms only .

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	11	0 ^[62]	0 ^[63]
Units: months				
median (full range (min-max))	6.0 (3.6 to 13.2)	6.0 (3.0 to 28.6)	(to)	(to)

Notes:

[62] - None of subjects showed complete response or partial response.

[63] - None of subjects showed complete response or partial response.

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2, C3: Overall Survival (OS)

End point title	Parts C1, C2, C3: Overall Survival (OS) ^[64]
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End point description:

OS time was defined as the time from the date of the first dose of a study drug to death due to any cause. mFAS: all enrolled subjects who satisfy both of following conditions: 1) Received at least 1 dose of study drug (M6620, gemcitabine, cisplatin/carboplatin with the actual amount greater than [$>$] 0 mg and/the duration of infusion $>$ 0 minutes; 2) Had a Baseline scan of disease assessment (Computed tomography [CT]/Magnetic resonance imaging [MRI]) with a measurable target lesion (sum of diameters of all target lesions $>$ 0 millimeter [mm]).

End point type	Secondary
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End point timeframe:

Time from first dose of study treatment to 4.3 years

Notes:

[64] - 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: In this endpoint, the data was planned to be reported for Parts C1, C2 and C3 arms only .

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	47	2	13
Units: months				
median (full range (min-max))	7.4 (0.8 to 28.2)	12.4 (1.4 to 31.6)	7.0 (6.3 to 7.0)	5.5 (0.8 to 16.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2, C3: Percentage of Subjects with Clinical benefit (Complete Response (CR) + Partial Response (PR) + Stable Disease (SD) of 6 months or

greater)

End point title	Parts C1, C2, C3: Percentage of Subjects with Clinical benefit (Complete Response (CR) + Partial Response (PR) + Stable Disease (SD) of 6 months or greater) ^[65]
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End point description:

Clinical benefit rate was defined as the proportion of subjects who achieved a BOR of CR, PR or SD greater than or equal to \geq 6 months. mFAS: all enrolled subjects who satisfy both of following conditions: 1) Received at least 1 dose of study drug (M6620, gemcitabine, cisplatin/carboplatin with the actual amount greater than $>$ 0 mg and/the duration of infusion $>$ 0 minutes; 2) Had a Baseline scan of disease assessment (Computed tomography [CT]/Magnetic resonance imaging [MRI]) with a measurable target lesion (sum of diameters of all target lesions $>$ 0 millimeter [mm]).

End point type	Secondary
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End point timeframe:

Time from first dose of study treatment to 4.3 years

Notes:

[65] - 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: In this endpoint, the data was planned to be reported for Parts C1, C2 and C3 arms only .

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	47	2	13
Units: percentage of subjects				
number (confidence interval 90%)	15.8 (7.1 to 28.8)	27.7 (17.2 to 40.3)	0 (0.0 to 77.6)	0 (0.0 to 20.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Maximum Observed Plasma Concentration (Cmax) of M6620

End point title	Parts C1, C2 and C3: Maximum Observed Plasma Concentration (Cmax) of M6620 ^[66]
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End point description:

Cmax was obtained directly from the concentration versus time curve. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount $>$ 0 mg and/or the duration of infusion $>$ 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[66] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: nanogram per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	882 (± 55.2)	555 (± 42.9)	683 (± 99999)	528 (± 46.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve from Time Zero to the Last Sampling Time (tlast) of M6620

End point title	Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve from Time Zero to the Last Sampling Time (tlast) of M6620 ^[67]
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End point description:

Area under the plasma concentration versus time curve from time zero to the last sampling time t at which the concentration was at or above the lower limit of quantification (LLQ). AUC_{0-t} was to be calculated according to the mixed log-linear trapezoidal rule. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "3.3333" signifies that median was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[67] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: hours				
median (full range (min-max))	4.00 (3.00 to 8.00)	4.00 (3.67 to 8.07)	3.3333 (2.00 to 4.00)	4.03 (3.68 to 8.00)

Statistical analyses

Secondary: Parts C1, C2 and C3: Time to Reach Maximum Plasma Concentration (Tmax) of M6620

End point title	Parts C1, C2 and C3: Time to Reach Maximum Plasma Concentration (Tmax) of M6620 ^[68]
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End point description:

Tmax is time to reach maximum observed plasma concentration obtained directly from the concentration versus time curve. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[68] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: hours				
median (full range (min-max))	0.917 (0.483 to 2.28)	0.917 (0.500 to 2.00)	0.742 (0.533 to 0.950)	0.967 (0.467 to 1.23)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve From Time Zero to 4 hours [hr] (AUC0-4hr) of M6620

End point title	Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve From Time Zero to 4 hours [hr] (AUC0-4hr) of M6620 ^[69]
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End point description:

Area under the plasma concentration-time curve from time 0 to 4 hours post-dose (AUC0-4) was calculated using the linear trapezoidal rule. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 4 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[69] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	34	2	12
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	1600 (± 35.8)	1110 (± 26.4)	1030 (± 99999)	693 (± 32.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve From Time Zero to 8 hours [hr] (AUC0-8 hr) of of M6620

End point title	Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve From Time Zero to 8 hours [hr] (AUC0-8 hr) of of M6620 ^[70]
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End point description:

Area under the plasma concentration-time curve from time 0 to 8 hours post-dose (AUC0-8) was calculated using the linear trapezoidal rule. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[70] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	0 ^[71]	2
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	2000 (± 10.9)	1800 (± 99999)	()	970 (± 99999)

Notes:

[71] - None of subjects were evaluable at the given timepoints.

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve From Time Zero to Last Sampling Time (AUC0-t) of of M6620

End point title	Parts C1, C2 and C3: Area Under the Plasma Concentration-Time Curve From Time Zero to Last Sampling Time (AUC0-t) of of M6620 ^[72]
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End point description:

Area under the plasma concentration versus time curve from time zero to the last sampling time t at which the concentration was at or above the lower limit of quantification (LLQ). AUC0-t was to be calculated according to the mixed log-linear trapezoidal rule. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3, and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[72] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: ng*hr/mL				
geometric mean (geometric coefficient of variation)	1660 (± 35.8)	1110 (± 28.8)	910 (± 99999)	730 (± 36.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Dose Normalized Maximum Concentration (Cmax/Dose_mg) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Maximum Concentration (Cmax/Dose_mg) of M6620 ^[73]
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End point description:

Dose normalized was calculated as Cmax obtained directly from the concentration versus time curve divided by dose. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3, and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[73] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: ng/mL/mg				
geometric mean (geometric coefficient of variation)	2.37 (± 52.4)	2.18 (± 44.6)	2.72 (± 99999)	3.24 (± 54.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Dose Normalized Maximum Concentration (Cmax/Dose_mg/m²) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Maximum Concentration (Cmax/Dose_mg/m ²) of M6620 ^[74]
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End point description:

Dose normalized was calculated as Cmax obtained directly from the concentration versus time curve divided by dose. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3, and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[74] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: ng/mL/(mg/m ²)				
geometric mean (geometric coefficient of variation)	4.28 (± 54.6)	3.97 (± 42.9)	4.89 (± 99999)	5.88 (± 47.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Dose Normalized Area Under The Concentration-Time Curve (AUC) from Start of Infusion to The 4 hour Sampling Time After Start of Infusion (AUC0-4h/Dose_mg) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Area Under The Concentration-Time Curve (AUC) from Start of Infusion to The 4 hour Sampling Time After Start of Infusion (AUC0-4h/Dose_mg) of M6620 ^[75]
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End point description:

Dose normalized was calculated as area under the plasma concentration-time curve from time zero to 4 hour postdose divided by dose. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 4 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[75] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	34	2	12
Units: ng*h/mL/mg				
geometric mean (geometric coefficient of variation)	4.29 (± 37.0)	4.41 (± 26.1)	4.11 (± 99999)	4.24 (± 39.8)

Statistical analyses

Secondary: Parts C1, C2 and C3: Dose Normalized Area Under the Concentration-Time Curve (AUC) from Start of Infusion to the 4 hour Sampling Time After Start of Infusion (AUC0-4h/Dose_mg/m²) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Area Under the Concentration-Time Curve (AUC) from Start of Infusion to the 4 hour Sampling Time After Start of Infusion (AUC0-4h/Dose_mg/m ²) of M6620 ^[76]
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End point description:

Dose normalized was calculated as area under the plasma concentration-time curve from rom start of infusion to the 4 hour postdose divided by dose. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 4 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[76] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	34	2	12
Units: ng·h/mL/(mg/m ²)				
geometric mean (geometric coefficient of variation)	7.76 (± 36.7)	7.95 (± 26.4)	7.40 (± 99999)	7.71 (± 33.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Dose Normalized Area Under the Concentration-Time Curve (AUC) from Start of Infusion to the 8 hour Sampling Time After Start of Infusion (AUC0-8h/Dose_mg) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Area Under the Concentration-Time Curve (AUC) from Start of Infusion to the 8 hour Sampling Time After Start of Infusion (AUC0-8h/Dose_mg) of M6620 ^[77]
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End point description:

Dose normalized was calculated as area under the plasma concentration-time curve from time zero to 8 hour postdose divided by dose. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary			
End point timeframe:				
Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)				
Notes:				
[77] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.				
End point values	Part C1: M6620 210 mg/m^2 + Gemcitabine 1000 mg/m^2	Part C2: M6620 140 mg/m^2 + Cisplatin 75 mg/m^2	Part C3: M6620 140 mg/m^2 + Cisplatin 75 mg/m^2	Part C3: M6620 90 mg/m^2 + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	0 ^[78]	2
Units: ng*h/mL/mg				
geometric mean (geometric coefficient of variation)	5.43 (± 10.1)	7.53 (± 99999)	()	5.63 (± 99999)

Notes:

[78] - None of the subjects were evaluable at given time points.

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Dose Normalized Area Under the Concentration-Time Curve (AUC) from Start of Infusion to the 8 hour Sampling Time After Start of Infusion (AUC0-8h/Dose_mg/m²) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Area Under the Concentration-Time Curve (AUC) from Start of Infusion to the 8 hour Sampling Time After Start of Infusion (AUC0-8h/Dose_mg/m ²) of M6620 ^[79]
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End point description:

Dose normalized was calculated as area under the plasma concentration-time curve from time zero to 8 hours postdose divided by dose. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3 and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[79] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	0 ^[80]	2
Units: ng·h/mL/(mg/m ²)				
geometric mean (geometric coefficient of variation)	9.54 (± 10.9)	12.9 (± 99999)	()	10.8 (± 99999)

Notes:

[80] - None of the subjects were evaluable at given time points.

Statistical analyses

No statistical analyses for this end point

Secondary: Parts C1, C2 and C3: Dose Normalized Area Under Concentration-Time Curve (AUC) from Time Zero to the Last Sampling Time (tlast) (AUC0-t/Dose_mg) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Area Under Concentration-Time Curve (AUC) from Time Zero to the Last Sampling Time (tlast) (AUC0-t/Dose_mg) of M6620 ^[81]
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End point description:

Area under the plasma concentration versus time curve from time zero to the last sampling time t at which the concentration was at or above the lower limit of quantification (LLQ). AUC0-t was to be calculated according to the mixed log-linear trapezoidal rule. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3, and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[81] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: ng·h/mL/mg				
geometric mean (geometric coefficient of variation)	4.47 (± 36.3)	4.36 (± 30.6)	3.62 (± 99999)	4.47 (± 41.7)

Statistical analyses

Secondary: Parts C1, C2 and C3: Dose Normalized Area Under Concentration-Time Curve (AUC) from Time Zero to the Last Sampling Time (tlast) (AUC0-t/Dose_mg/m²) of M6620

End point title	Parts C1, C2 and C3: Dose Normalized Area Under Concentration-Time Curve (AUC) from Time Zero to the Last Sampling Time (tlast) (AUC0-t/Dose_mg/m ²) of M6620 ^[82]
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End point description:

Area under the plasma concentration versus time curve from time zero to the last sampling time t at which the concentration was at or above the lower limit of quantification (LLQ). AUC0-t was to be calculated according to the mixed log-linear trapezoidal rule. PAS included all subjects who received at least 1 dose of M6620 (with the actual amount > 0 mg and/or the duration of infusion > 0 minutes), and provided at least 1 measurable post-dose concentration. Here, "number of subjects analyzed" signifies those subjects who were evaluable for this endpoint at given time points. Here, "99999" signifies that geometric coefficient of variation was not calculated.

End point type	Secondary
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End point timeframe:

Pre-infusion, 0.5, 1, 2, 3, and 7 hours after end of infusion (EOI) on Cycle 1 Day 2 (each cycle is of 21 days)

Notes:

[82] - 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: In this endpoint, we have reported data for Parts C1, C2 and C3 arms only. For Part A1, A2, B1 and B2 arms we have created separate endpoints.

End point values	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	37	2	12
Units: ng·h/mL/(mg/m ²)				
geometric mean (geometric coefficient of variation)	8.08 (± 36.7)	7.92 (± 28.8)	6.51 (± 99999)	8.12 (± 36.1)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Parts A1, A2 and B1: Time from first dose of study treatment up to 4.6 years; Part B2: Time from first dose of study treatment up to 1.6 years; Parts C1, C2 and C3: Time from first dose of study treatment up to 4.3 years.

Adverse event reporting additional description:

Non-serious Adverse Event Section: Treatment-Emergent Adverse Events were reported for Parts A1, A2 and B1 and Non-serious Adverse event for Parts B2, C1, C2 and C3 with same threshold frequency (0%).

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	18,22.1&21

Reporting groups

Reporting group title	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at a initial dose of 18 milligrams per square meter (mg/m²) approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at escalated dose of 36 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at escalated dose of 60 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at escalated dose of 72 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at escalated dose of 90 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at escalated dose of 140 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 500 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²
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Reporting group description:

Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 750 mg/m² on Days 1 and 8 of a 21-day cycle up to 61 weeks.

Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at escalated dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m ² on Days 1 and 8 of a 21-day cycle up to 61 weeks.	
Reporting group title	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 90 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 and Cisplatin at a dose of 60 mg/m ² on Day 1, of a 21-day cycle up to 41 weeks.	
Reporting group title	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 120 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Gemcitabine at a dose of 875 mg/m ² on Days 1 and 8 and Cisplatin at a dose of 60 mg/m ² on Day 1, of a 21-day cycle up to 41 weeks.	
Reporting group title	Part B1: M6620 140 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 140 mg/m ² approximately for 24 hours later on Days 2 and 9 of a 21-day cycle up to 74 weeks.	
Reporting group title	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 90 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin at a dose of 40 mg/m ² on Day 1, of a 21-day cycle up to 74 weeks.	
Reporting group title	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 140mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin ata dose of 40 mg/m ² on Day 1 of a 21-day cycle for up to 74 weeks.	
Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin at a dose of 40 mg/m ² on Day 1 of a 21-day cycle up to 74 weeks.	
Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with 60 mg/m ² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.	
Reporting group title	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 140 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with 75 mg/m ² of Cisplatin on Day 1 of a 21-day cycle up to 74 weeks.	
Reporting group title	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at dose of 210 mg/m ² approximately for 24 hours later on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m ² on Day 1 of a 21-day cycle up to 74 weeks.	
Reporting group title	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²
Reporting group description: Subjects received intravenous infusion of M6620 at a dose of 60 mg/m ² , in combination with irinotecan at a dose of 180 mg/m ² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.	

Reporting group title	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
Reporting group description:	
Subjects received intravenous infusion of M6620 at a dose of 90 mg/m ² , in combination with irinotecan at a dose of 180 mg/m ² (over 90 minutes) on Days 1 and 15 of a 28-day cycle up to 72 weeks.	
Reporting group title	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²
Reporting group description:	
Subjects with advanced non-small cell lung cancer (NSCLC) received intravenous infusion of M6620 at a dose of 210 mg/m ² on Days 2 and 9 in combination with Gemcitabine at a dose of 1000 mg/m ² on Days 1 and 8 of a 21-day cycle up to 63 weeks.	
Reporting group title	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Reporting group description:	
Subjects with advanced triple negative breast cancer (TNBC) received intravenous infusion of M6620 at a dose of 140 mg/m ² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m ² on Day 1 of a 21-day cycle up to 137 weeks.	
Reporting group title	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Reporting group description:	
Subjects with platinum-resistant advanced small cell lung cancer (SCLC) received intravenous infusion of M6620 at a dose of 140 mg/m ² on Days 2 and 9 in combination with Cisplatin at a dose of 75 mg/m ² on Day 1 of a 21-day cycle up to 27 weeks.	
Reporting group title	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL
Reporting group description:	
Subjects with platinum-resistant advanced SCLC received intravenous infusion of M6620 at a dose of 90 mg/m ² on Days 2 and 9 in combination with Carboplatin area under concentration-time curve (AUC) at a dose of 5 milligrams·minute per milliliter on Day 1 of a 21-day cycle up to 27 weeks.	

Serious adverse events	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	2 / 4 (50.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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			
Hypovolaemic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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			
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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			
Atrial flutter			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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			
Serotonin syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small intestine obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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			
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (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			
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (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
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
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	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)	3 / 6 (50.00%)	5 / 8 (62.50%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Vascular disorders			
Hypovolaemic shock			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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			
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences causally related to treatment / all	0 / 0	1 / 1	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
Pleuritic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (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			
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic transfusion reaction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (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			
Atrial flutter			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 arrest			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pericardial effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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			
Serotonin syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Thrombocytopenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (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
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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			
Portal vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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			
Flank pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
Pelvic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (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
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
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	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	3 / 7 (42.86%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Brain neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Metastases to liver			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Non-small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Hypovolaemic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Deep vein thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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 oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Allergic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Left ventricular hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pericardial effusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Nervous system disorders			
Serotonin syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 / 3 (0.00%)	0 / 3 (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
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Small intestine obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			

Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	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
Muscular weakness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Escherichia sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Pelvic infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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	0 / 3 (0.00%)	0 / 3 (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
Sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (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
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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	0 / 3 (0.00%)	0 / 3 (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
Mastoiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Otitis media acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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 sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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			
Dehydration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Failure to thrive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (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

Serious adverse events	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	3 / 6 (50.00%)	2 / 2 (100.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypovolaemic shock			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic transfusion reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial flutter			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Serotonin syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Anaemia	subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
	occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia	subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
	occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura	subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders				
Diplopia	subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders				
Abdominal pain	subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea	subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small intestine obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypovolaemic shock			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Serotonin syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine obstruction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	4 / 10 (40.00%)	3 / 7 (42.86%)
number of deaths (all causes)	0	0	0
number of deaths resulting from			

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Brain neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Metastases to liver			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Non-small cell lung cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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			
Hypovolaemic shock			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Superior vena cava syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Deep vein thrombosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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			
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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

Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	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
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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 / 4 (0.00%)	0 / 10 (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 oedema			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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 failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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 / 4 (0.00%)	1 / 10 (10.00%)	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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	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
Body temperature increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
cardiac arrest			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Left ventricular hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Nervous system disorders			
Serotonin syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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

Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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 / 4 (0.00%)	0 / 10 (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
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	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
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Small intestine obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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			

Portal vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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			
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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 pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Muscular weakness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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			
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Pelvic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Pneumonia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	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
Gastrointestinal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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	0 / 4 (0.00%)	0 / 10 (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
Mastoiditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Otitis media acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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 sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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			
Dehydration			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Failure to thrive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (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

Serious adverse events	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 5 (20.00%)	2 / 3 (66.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypovolaemic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial flutter			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Serotonin syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Anaemia	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders				
Diplopia	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders				
Abdominal pain	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea	subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	2 / 3 (66.67%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small intestine obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 38 (63.16%)	15 / 47 (31.91%)	0 / 2 (0.00%)
number of deaths (all causes)	4	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to liver			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypovolaemic shock			

subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 38 (5.26%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			

subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	4 / 38 (10.53%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (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
Pleural effusion			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergic transfusion reaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac arrest			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pericardial effusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Serotonin syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Thrombocytopenia			
subjects affected / exposed	3 / 38 (7.89%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	3 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine obstruction			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rectal haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 38 (5.26%)	3 / 47 (6.38%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 2	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Portal vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Flank pain			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	4 / 38 (10.53%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (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
Skin infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			

subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 13 (23.08%)		
number of deaths (all causes)	1		

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases to central nervous system			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain neoplasm			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to liver			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-small cell lung cancer			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypovolaemic shock			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Superior vena cava syndrome			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza like illness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaise			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stridor			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atelectasis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleuritic pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Body temperature increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Allergic transfusion reaction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cardiac arrest			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular hypertrophy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Serotonin syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Hemiparesis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small intestine obstruction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			

Portal vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash erythematous			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Flank pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular weakness			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pathological fracture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia sepsis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral candidiasis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal sepsis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	1 / 1		
Hypokalaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part A1: M6620 18 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 36 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 60 mg/m ² + Gemcitabine 875 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Brain neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastases to peritoneum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
White coat hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Peripheral coldness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Superior vena cava occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	2	2	1
Influenza like illness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Catheter site pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Device occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site induration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Reproductive system and breast disorders			
Balanoposthitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Prostatism subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Testicular pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Testicular swelling subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Menstruation irregular subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Metrorrhagia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Epistaxis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Laryngeal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nasal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rales			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dissociation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	2
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Platelet count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood sodium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood Chloride Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Left ventricular hypertrophy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Pericardial effusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Ventricular arrhythmia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Nervous system disorders			
Amnesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	1 / 4 (25.00%) 1
Dysgeusia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	2 / 4 (50.00%) 2
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Serotonin syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anameia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hearing impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid odema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Foreign body sensation in eyes subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Constipation subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 3 (33.33%) 1	2 / 4 (50.00%) 2
Diarrhoea subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	2 / 4 (50.00%) 2
Dyspepsia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1
Dysphagia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	2 / 3 (66.67%) 2	3 / 4 (75.00%) 3
Stomatitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	3 / 3 (100.00%) 3	3 / 4 (75.00%) 3
Abdominal distension			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Faeces discoloured			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Small intestine obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			

<p>alternative dictionary used: MedDRA 18,22.1&21</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Oesophageal obstruction</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Oral dysaesthesia</p> <p>alternative dictionary used: MedDRA 18,22.1&21</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Tongue ulceration</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Hepatobiliary disorders</p> <p>Hyperbilirubinaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Hepatomegaly</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Portal vein thrombosis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Skin and subcutaneous tissue disorders</p> <p>Alopecia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Erythema</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p>
<p>Hyperhidrosis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>1 / 4 (25.00%)</p> <p>1</p>
<p>Pruritus</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>

Rash			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myopathy			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Injection site cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest wall abscess			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Vaginal infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	2 / 3 (66.67%) 2	0 / 4 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 3 (33.33%) 1	0 / 4 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0
Hypovolaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A1: M6620 72 mg/m ² + Gemcitabine 875 mg/m ²	Part A1: M6620 90 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 140 mg/m ² + Gemcitabine 500 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)	6 / 6 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Non-small cell lung cancer			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Tumour pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Brain neoplasm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metastases to peritoneum			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Jugular vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
White coat hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Superior vena cava occlusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Chills			

subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	6 / 8 (75.00%)
occurrences (all)	2	3	6
Influenza like illness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Injection site reaction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 6 (50.00%)	4 / 8 (50.00%)
occurrences (all)	1	3	4
Face oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Infusion site reaction			

subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Infusion site erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Catheter site rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Device occlusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	0
Infusion site discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion site rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Injection site phlebitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site induration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Extravasation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thirst			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Drug hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Prostatism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Testicular swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Breast pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 7 (28.57%)	2 / 6 (33.33%)	3 / 8 (37.50%)
occurrences (all)	2	2	3
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	0 / 8 (0.00%)
occurrences (all)	2	3	0
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Rhinorrhoea			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Laryngeal oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dissociation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	4 / 6 (66.67%)	5 / 8 (62.50%)
occurrences (all)	1	4	5
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 7 (14.29%)	4 / 6 (66.67%)	3 / 8 (37.50%)
occurrences (all)	1	4	3
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences (all)	2	1	3
Blood bilirubin increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Platelet count increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Transaminases increased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Blood calcium decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
White blood cell count increased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Bacterial test positive			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Blood calcium increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Blood magnesium decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Blood phosphorus decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Blood sodium decreased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	0 / 8 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 0	0 / 8 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Neutrophil count increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Fibrin D dimer increased subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Prothrombin time prolonged subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Respiratory rate increased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood Chloride Decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Animal bite			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Sinus bradycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pericardial effusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Dysgeusia			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	4 / 8 (50.00%)
occurrences (all)	1	1	4
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 7 (14.29%)	2 / 6 (33.33%)	4 / 8 (50.00%)
occurrences (all)	1	2	4
Neurotoxicity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Serotonin syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sciatica			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Migraine			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 7 (57.14%)	2 / 6 (33.33%)	4 / 8 (50.00%)
occurrences (all)	4	2	4
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Thrombocytopenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Iron deficiency anameia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Pancytopenia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Ear and labyrinth disorders			
Deafness subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Hyperacusis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
External ear inflammation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	0 / 8 (0.00%) 0
Hearing impaired			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Visual impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Eyelid odema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	2 / 6 (33.33%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	2 / 7 (28.57%)	2 / 6 (33.33%)	2 / 8 (25.00%)
occurrences (all)	2	2	2
Diarrhoea			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	2 / 8 (25.00%)
occurrences (all)	2	3	2
Dyspepsia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 7 (42.86%)	3 / 6 (50.00%)	5 / 8 (62.50%)
occurrences (all)	3	3	5
Stomatitis			
subjects affected / exposed	2 / 7 (28.57%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	2
Vomiting			
subjects affected / exposed	2 / 7 (28.57%)	3 / 6 (50.00%)	2 / 8 (25.00%)
occurrences (all)	2	3	2
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Retching			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Oral pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Odynophagia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Small intestine obstruction			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eruption			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oesophageal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Rash maculo-papular			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Swelling face			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Decubitus ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Back pain			
subjects affected / exposed	3 / 7 (42.86%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	3	1	1
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	2 / 8 (25.00%)
occurrences (all)	0	1	2
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			

subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Pain in jaw			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pathological fracture			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	2 / 6 (33.33%) 2	3 / 8 (37.50%) 3
Lung infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 6 (16.67%) 1	0 / 8 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	1 / 6 (16.67%) 1	2 / 8 (25.00%) 2
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 7 (14.29%) 1	0 / 6 (0.00%) 0	1 / 8 (12.50%) 1
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Localised infection subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0
Oral herpes subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 6 (0.00%) 0	0 / 8 (0.00%) 0

Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	1	0	2
Chest wall abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Oesophageal candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Influenza			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 7 (42.86%)	1 / 6 (16.67%)	3 / 8 (37.50%)
occurrences (all)	3	1	3
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypokalaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Hypomagnesaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	2	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hyperalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 7 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A1: M6620 210 mg/m ² + Gemcitabine 500 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 750 mg/m ²	Part A1: M6620 210 mg/m ² + Gemcitabine 875 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Brain neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to peritoneum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Flushing			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hot flush			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White coat hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peripheral coldness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Superior vena cava occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	6 / 7 (85.71%)
occurrences (all)	3	3	6
Influenza like illness			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peripheral swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Catheter site related reaction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device occlusion			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypothermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Infusion site rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site induration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site mass			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prostatism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wheezing			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laryngeal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Atelectasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphonia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Insomnia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dissociation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	4 / 7 (57.14%)
occurrences (all)	2	2	4
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	3 / 7 (42.86%)
occurrences (all)	1	2	3
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 3 (100.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

White blood cell count increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Bacterial test positive subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Blood calcium increased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Blood magnesium decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Blood phosphorus decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Blood sodium decreased subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Neutrophil count increased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood Chloride Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Procedural headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	2 / 3 (66.67%)	2 / 3 (66.67%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Neurotoxicity			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Serotonin syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vocal cord paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 3 (66.67%)	3 / 3 (100.00%)	4 / 7 (57.14%)
occurrences (all)	2	3	4
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Neutropenia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Thrombocytopenia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anameia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hearing impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid odema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Abdominal pain upper			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 7 (42.86%)
occurrences (all)	1	1	3
Diarrhoea			

subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	3 / 3 (100.00%)	4 / 7 (57.14%)
occurrences (all)	2	3	4
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	2 / 7 (28.57%)
occurrences (all)	1	2	2
Abdominal distension			
subjects affected / exposed	2 / 3 (66.67%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Gingival bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Small intestine obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			

Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin disorder			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Urine flow decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Incontinence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Micturition urgency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Urinary hesitation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Urinary tract pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 3 (0.00%) 0	2 / 7 (28.57%) 2
Back pain subjects affected / exposed occurrences (all)	3 / 3 (100.00%) 3	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Musculoskeletal pain			

subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Myopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Chest wall abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Genital candidiasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Infected skin ulcer infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pelvic infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Perichondritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Device related infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Enteritis infectious subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Gingivitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Mastitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Mastoiditis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Vaginal infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 3 (33.33%) 1	3 / 7 (42.86%) 3
Dehydration subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	1 / 7 (14.29%) 1
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0	0 / 7 (0.00%) 0
Hyperkalaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part A1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part A2: M6620 90 mg/m ² + Gemcitabine + Cisplatin	Part A2: M6620 120 mg/m ² + Gemcitabine + Cisplatin
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	6 / 6 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Brain neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metastases to peritoneum			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
White coat hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Embolism			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Superior vena cava occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 6 (66.67%)	6 / 6 (100.00%)	2 / 2 (100.00%)
occurrences (all)	4	6	2
Influenza like illness			
subjects affected / exposed	4 / 6 (66.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
Injection site reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	3 / 6 (50.00%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	3	2	1
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site reaction			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Infusion site erythema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Device occlusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site rash			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Injection site phlebitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Catheter site pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site induration			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Extravasation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Balanoposthitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Prostatism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 6 (50.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Epistaxis			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Haemoptysis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	3 / 6 (50.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	3	0	1
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Laryngeal oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Pleuritic pain			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Asthma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Sputum increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Hallucination			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dissociation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 6 (66.67%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	4	2	1
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 6 (50.00%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	3	2	1
Blood alkaline phosphatase increased			

subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences (all)	2	1	1
Blood bilirubin increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0

Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood Chloride Decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amylase increased			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Animal bite			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Pericardial effusion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Ventricular arrhythmia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders			
Amnesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 6 (33.33%) 2	1 / 2 (50.00%) 1
Dysgeusia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 6 (0.00%) 0	1 / 2 (50.00%) 1
Neuropathy peripheral subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	1 / 6 (16.67%) 1	0 / 2 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 6 (0.00%) 0	0 / 2 (0.00%) 0
Neuralgia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	1	2	1
Neurotoxicity			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Serotonin syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Parosmia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 6 (83.33%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	5	2	1

Leukopenia			
subjects affected / exposed	3 / 6 (50.00%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences (all)	3	1	1
Neutropenia			
subjects affected / exposed	4 / 6 (66.67%)	4 / 6 (66.67%)	1 / 2 (50.00%)
occurrences (all)	4	4	1
Thrombocytopenia			
subjects affected / exposed	3 / 6 (50.00%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	3	2	1
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anameia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
External ear inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hearing impaired			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Visual impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Photopsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eyelid odema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	1	2	1
Diarrhoea			
subjects affected / exposed	1 / 6 (16.67%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Dyspepsia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	1
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 6 (66.67%)	5 / 6 (83.33%)	2 / 2 (100.00%)
occurrences (all)	4	5	2
Stomatitis			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)	3 / 6 (50.00%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Small intestine obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
alternative dictionary used: MedDRA 18,22.1&21			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oesophageal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nocturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Proteinuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Lung infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection subjects affected / exposed	3 / 6 (50.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Urinary tract infection subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	1 / 2 (50.00%)
occurrences (all)	1	2	1
Viral upper respiratory tract infection subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes zoster subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Localised infection subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral herpes subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth infection subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral infection subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Breast abscess subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Injection site cellulitis subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest wall abscess			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Vulvovaginal candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 2 (50.00%)
occurrences (all)	2	1	1
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hypomagnesaemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hyponatraemia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B1: M6620 140 mg/m ²	Part B1: M6620 90 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 40 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Brain neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastases to peritoneum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Jugular vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White coat hypertension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Superior vena cava occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	0 / 4 (0.00%)	3 / 3 (100.00%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Infusion site extravasation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site induration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Extravasation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Laryngeal oedema			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dissociation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Blood phosphorus decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood sodium decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Neutrophil count increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Fibrin D dimer increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Prothrombin time prolonged subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Respiratory rate increased subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 3 (0.00%) 0	0 / 3 (0.00%) 0
Weight increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood Chloride Decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Headache			

subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Serotonin syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anameia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
External ear inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hearing impaired			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Neurosensory hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid odema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Photophobia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	2 / 3 (66.67%)
occurrences (all)	1	2	2
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Small intestine obstruction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eruption			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urine flow decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest wall abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Pelvic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Mastitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	3 / 3 (100.00%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	1	1	2
Hypomagnesaemia			

subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hyponatraemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B1: M6620 210 mg/m ² + Cisplatin 40 mg/m ²	Part B1: M6620 210 mg/m ² + Cisplatin 60 mg/m ²	Part B1: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	10 / 10 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Brain neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Metastases to peritoneum			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 4 (25.00%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	2 / 7 (28.57%)
occurrences (all)	0	1	2

Jugular vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 4 (25.00%)	1 / 10 (10.00%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
White coat hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Superior vena cava occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	4 / 10 (40.00%)	4 / 7 (57.14%)
occurrences (all)	2	4	4
Influenza like illness			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Face oedema			

subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Infusion site extravasation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device occlusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site discomfort			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Infusion site pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Catheter site bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site induration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Extravasation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Localised oedema subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Thirst subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	1 / 7 (14.29%) 1
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Reproductive system and breast disorders Balanoposthitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Prostatism subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Testicular pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Testicular swelling subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Menstruation irregular			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Laryngeal oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Nasal ulcer			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Sleep apnoea syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dissociation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	3 / 10 (30.00%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Platelet count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Blood calcium increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Blood magnesium decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Blood phosphorus decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Blood sodium decreased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Blood urea increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Body temperature increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Neutrophil count increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Fibrin D dimer increased subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Prothrombin time prolonged			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Blood Chloride Decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood cholesterol increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural			

complications			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	1 / 4 (25.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Palpitations			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ventricular arrhythmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	3 / 4 (75.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	3	1	1
Dysgeusia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	2 / 4 (50.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Poor quality sleep			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Serotonin syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parosmia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hemiparesis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Brain oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	5 / 10 (50.00%)	6 / 7 (85.71%)
occurrences (all)	1	5	6
Leukopenia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Neutropenia			
subjects affected / exposed	1 / 4 (25.00%)	6 / 10 (60.00%)	1 / 7 (14.29%)
occurrences (all)	1	6	1
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Thrombocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Iron deficiency anameia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 10 (10.00%) 1	0 / 7 (0.00%) 0
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Pancytopenia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Ear and labyrinth disorders			
Deafness subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	1 / 7 (14.29%) 1
Hyperacusis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 1	0 / 10 (0.00%) 0	3 / 7 (42.86%) 3
External ear inflammation subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Middle ear inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hearing impaired			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Eye irritation			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Eyelid odema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 4 (50.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	5 / 10 (50.00%)	2 / 7 (28.57%)
occurrences (all)	1	5	2
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	1 / 10 (10.00%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dysphagia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 4 (50.00%)	4 / 10 (40.00%)	4 / 7 (57.14%)
occurrences (all)	4	4	1
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	2 / 10 (20.00%)	3 / 7 (42.86%)
occurrences (all)	1	2	3
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematochezia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Retching			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oral pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			

subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Small intestine obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Portal vein thrombosis			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 10 (0.00%) 0	0 / 7 (0.00%) 0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Proteinuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neck pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Limb discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Chest wall abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Device related infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Gingivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mastoiditis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	3
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Hypocalcaemia			

subjects affected / exposed	0 / 4 (0.00%)	2 / 10 (20.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 10 (30.00%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypovolaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 10 (10.00%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Fluid retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 10 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B1: M6620 210 mg/m ² + Cisplatin 75 mg/m ²	Part B2: M6620 60 mg/m ² + Irinotecan 180 mg/m ²	Part B2: M6620 90 mg/m ² + Irinotecan 180 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	5 / 5 (100.00%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Brain neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metastases to peritoneum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flushing			

subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jugular vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular compression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
White coat hypertension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lymphoedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Superior vena cava occlusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vein disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	2 / 5 (40.00%)	2 / 3 (66.67%)
occurrences (all)	3	2	2
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion site reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Device occlusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site induration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Extravasation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prostatism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Testicular pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	3 / 5 (60.00%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Productive cough			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Laryngeal oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Atelectasis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasal ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dissociation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	3 / 3 (100.00%)
occurrences (all)	1	0	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Blood creatinine increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
White blood cell count decreased			
subjects affected / exposed	1 / 3 (33.33%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Platelet count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Transaminases increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Neutrophil count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Chloride Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood pressure decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Troponin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Allergic transfusion reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural headache			

subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Procedural pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Spinal fracture subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Cardiac disorders			
Palpitations subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 5 (0.00%) 0	1 / 3 (33.33%) 1
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Extrasystoles subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Left ventricular hypertrophy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Pericardial effusion subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0

Ventricular arrhythmia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Nervous system disorders			
Amnesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	1 / 3 (33.33%) 1
Neuropathy peripheral subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Neuralgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	1 / 3 (33.33%) 1
Poor quality sleep subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Post herpetic neuralgia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Serotonin syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Brain oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hemiparaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 5 (40.00%)	2 / 3 (66.67%)
occurrences (all)	1	2	2
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	2	1	1

Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Febrile neutropenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Iron deficiency anameia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Pancytopenia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Ear and labyrinth disorders			
Deafness subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Hyperacusis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
External ear inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Middle ear inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hearing impaired			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid odema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foreign body sensation in eyes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 3 (66.67%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	2	2	0
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	4 / 5 (80.00%)	1 / 3 (33.33%)
occurrences (all)	1	4	1
Diarrhoea			
subjects affected / exposed	2 / 3 (66.67%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	2	2	1
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	3 / 5 (60.00%)	2 / 3 (66.67%)
occurrences (all)	1	3	2
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Abdominal distension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Oral disorder			

subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Odynophagia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Small intestine obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral dysaesthesia			
alternative dictionary used: MedDRA 18,22.1&21			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Portal vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Swelling face			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nail ridging			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cold sweat			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Petechiae			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Chronic kidney disease subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Renal impairment subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Urine flow decreased subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Incontinence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Micturition urgency subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Urinary hesitation subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Urinary incontinence subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Urinary tract pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 5 (20.00%) 1	0 / 3 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 5 (20.00%) 1	0 / 3 (0.00%) 9
Musculoskeletal chest pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Myopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Soft tissue swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Breast abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injection site cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest wall abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Escherichia sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Catheter site infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Device related infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Enteritis infectious subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Gingivitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Mastitis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Mastoiditis subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Otitis media subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Vaginal infection subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 5 (0.00%) 0	0 / 3 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	2 / 3 (66.67%) 2	1 / 5 (20.00%) 1	1 / 3 (33.33%) 1
Dehydration			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	2
Hyponatraemia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	2	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypovolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Fluid retention			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part C1: M6620 210 mg/m ² + Gemcitabine 1000 mg/m ²	Part C2: M6620 140 mg/m ² + Cisplatin 75 mg/m ²	Part C3: M6620 140 mg/m ² + Cisplatin 75 mg/m ²
Total subjects affected by non-serious adverse events			
subjects affected / exposed	37 / 38 (97.37%)	47 / 47 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-small cell lung cancer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metastases to central nervous system			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Brain neoplasm subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Metastases to peritoneum subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Vascular disorders			
Deep vein thrombosis subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	3 / 47 (6.38%) 3	0 / 2 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	5 / 47 (10.64%) 5	0 / 2 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	4 / 47 (8.51%) 4	0 / 2 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	4 / 47 (8.51%) 4	0 / 2 (0.00%) 0
Jugular vein thrombosis subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	1 / 2 (50.00%) 1
Vascular compression subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	1 / 2 (50.00%) 1
Hypotension subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
White coat hypertension subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Lymphoedema subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Peripheral coldness			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Embolism			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Subclavian vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Superior vena cava occlusion			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Thrombophlebitis			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Vein disorder			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 38 (7.89%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Chills			
subjects affected / exposed	4 / 38 (10.53%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	4	2	0
Fatigue			
subjects affected / exposed	21 / 38 (55.26%)	32 / 47 (68.09%)	2 / 2 (100.00%)
occurrences (all)	21	32	2
Influenza like illness			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Injection site reaction			

subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	4 / 38 (10.53%)	6 / 47 (12.77%)	0 / 2 (0.00%)
occurrences (all)	4	6	0
Oedema peripheral			
subjects affected / exposed	6 / 38 (15.79%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	6	4	0
Pain			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Peripheral swelling			
subjects affected / exposed	1 / 38 (2.63%)	3 / 47 (6.38%)	0 / 2 (0.00%)
occurrences (all)	1	3	0
Pyrexia			
subjects affected / exposed	12 / 38 (31.58%)	7 / 47 (14.89%)	0 / 2 (0.00%)
occurrences (all)	12	7	0
Face oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Infusion site reaction			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Infusion site erythema			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Catheter site pain			

subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Catheter site rash			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site related reaction			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Chest discomfort			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Device occlusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypothermia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site rash			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injection site phlebitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Catheter site pruritus			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion site pruritus			

subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Catheter site bruise			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Catheter site induration			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Catheter site inflammation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Extravasation			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Injection site mass			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Injection site pruritus			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Localised oedema			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Thirst			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Drug hypersensitivity			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0

Seasonal allergy subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Reproductive system and breast disorders			
Balanoposthitis subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Prostatism subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Testicular pain subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Testicular swelling subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Breast pain subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	2 / 47 (4.26%) 2	0 / 2 (0.00%) 0
Menstruation irregular subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Metrorrhagia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Pelvic pain subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Vaginal haemorrhage subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	5 / 38 (13.16%) 5	8 / 47 (17.02%) 8	1 / 2 (50.00%) 1
Epistaxis			

subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Haemoptysis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Nasal congestion			
subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Productive cough			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Wheezing			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Dyspnoea			
subjects affected / exposed	14 / 38 (36.84%)	7 / 47 (14.89%)	0 / 2 (0.00%)
occurrences (all)	14	7	0
Hypoxia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Laryngeal oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Pleuritic pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			

subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Pulmonary embolism			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Asthma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	14 / 38 (36.84%)	7 / 47 (14.89%)	0 / 2 (0.00%)
occurrences (all)	14	7	0
Hiccups			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nasal ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sputum increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Rhinitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rales			

subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Respiratory failure			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 38 (5.26%)	6 / 47 (12.77%)	0 / 2 (0.00%)
occurrences (all)	2	6	0
Depression			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 38 (5.26%)	3 / 47 (6.38%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Depressed mood			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dissociation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	10 / 38 (26.32%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	10	1	0
Aspartate aminotransferase increased			

subjects affected / exposed	11 / 38 (28.95%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	11	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	3 / 38 (7.89%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 38 (5.26%)	2 / 47 (4.26%)	1 / 2 (50.00%)
occurrences (all)	2	2	1
Lipase increased			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Neutrophil count decreased			
subjects affected / exposed	1 / 38 (2.63%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
Platelet count decreased			
subjects affected / exposed	3 / 38 (7.89%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Weight decreased			
subjects affected / exposed	1 / 38 (2.63%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
White blood cell count decreased			
subjects affected / exposed	8 / 38 (21.05%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	8	4	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0

Platelet count increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Transaminases increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood calcium decreased			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
White blood cell count increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial test positive			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eastern Cooperative Oncology Group performance status worsened			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Fibrin D dimer increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Prothrombin time prolonged			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Weight increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood Chloride Decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Blood pressure decreased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Glomerular filtration rate increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Troponin increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Infusion related reaction			
subjects affected / exposed	2 / 38 (5.26%)	7 / 47 (14.89%)	0 / 2 (0.00%)
occurrences (all)	2	7	0
Contusion			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Muscle strain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Allergic transfusion reaction			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural headache			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Spinal fracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 38 (0.00%)	3 / 47 (6.38%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Sinus bradycardia			
subjects affected / exposed	0 / 38 (0.00%)	3 / 47 (6.38%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Sinus tachycardia			
subjects affected / exposed	3 / 38 (7.89%)	3 / 47 (6.38%)	0 / 2 (0.00%)
occurrences (all)	3	3	0
Tachycardia			
subjects affected / exposed	3 / 38 (7.89%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Extrasystoles			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Left ventricular hypertrophy subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Pericardial effusion subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Ventricular arrhythmia subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders			
Amnesia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Balance disorder subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Dizziness subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	11 / 47 (23.40%) 11	0 / 2 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	9 / 47 (19.15%) 9	0 / 2 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	8 / 38 (21.05%) 8	18 / 47 (38.30%) 18	0 / 2 (0.00%) 0
Neuropathy peripheral subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	8 / 47 (17.02%) 8	0 / 2 (0.00%) 0
Paraesthesia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	4 / 47 (8.51%) 4	0 / 2 (0.00%) 0
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 38 (0.00%)	8 / 47 (17.02%)	0 / 2 (0.00%)
occurrences (all)	0	8	0
Neuralgia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Poor quality sleep			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neurotoxicity			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Serotonin syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Vocal cord paralysis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hemiparesis			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral motor neuropathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Aphasia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Brain oedema			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hemiparaesthesia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hyperaesthesia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Memory impairment			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Sinus headache			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	19 / 38 (50.00%)	19 / 47 (40.43%)	1 / 2 (50.00%)
occurrences (all)	19	19	1
Leukopenia			
subjects affected / exposed	3 / 38 (7.89%)	5 / 47 (10.64%)	0 / 2 (0.00%)
occurrences (all)	3	5	0
Neutropenia			
subjects affected / exposed	11 / 38 (28.95%)	29 / 47 (61.70%)	1 / 2 (50.00%)
occurrences (all)	11	29	1
Thrombocytopenia			
subjects affected / exposed	12 / 38 (31.58%)	9 / 47 (19.15%)	1 / 2 (50.00%)
occurrences (all)	12	9	1
Febrile neutropenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Thrombocytosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anameia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Increased tendency to bruise			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pancytopenia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 38 (0.00%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Ear discomfort			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperacusis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Tinnitus			
subjects affected / exposed	1 / 38 (2.63%)	21 / 47 (44.68%)	1 / 2 (50.00%)
occurrences (all)	1	21	1
External ear inflammation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Middle ear inflammation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hearing impaired			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoacusis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eye disorders			

Vision blurred			
subjects affected / exposed	0 / 38 (0.00%)	3 / 47 (6.38%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Visual impairment			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lacrimation increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eyelid odema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Diplopia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eye haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Foreign body sensation in eyes subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	5 / 47 (10.64%) 5	1 / 2 (50.00%) 1
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	3 / 47 (6.38%) 3	1 / 2 (50.00%) 1
Constipation subjects affected / exposed occurrences (all)	6 / 38 (15.79%) 6	14 / 47 (29.79%) 14	2 / 2 (100.00%) 2
Diarrhoea subjects affected / exposed occurrences (all)	5 / 38 (13.16%) 5	16 / 47 (34.04%) 16	0 / 2 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	5 / 47 (10.64%) 5	0 / 2 (0.00%) 0
Dysphagia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Nausea subjects affected / exposed occurrences (all)	15 / 38 (39.47%) 15	39 / 47 (82.98%) 39	1 / 2 (50.00%) 1
Stomatitis subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	6 / 47 (12.77%) 6	0 / 2 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	11 / 38 (28.95%) 11	28 / 47 (59.57%) 28	1 / 2 (50.00%) 1
Abdominal distension			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Haematochezia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oral disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia oral			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Retching			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Oral pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Faeces discoloured			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Salivary hypersecretion			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Small intestine obstruction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eructation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Gingival pain			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Gingival swelling			

alternative dictionary used: MedDRA 18,22.1&21 subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Oesophageal obstruction subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Oral dysaesthesia alternative dictionary used: MedDRA 18,22.1&21 subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Tongue ulceration subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Hepatomegaly subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Portal vein thrombosis subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	7 / 47 (14.89%) 7	0 / 2 (0.00%) 0
Erythema subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	3 / 47 (6.38%) 3	0 / 2 (0.00%) 0
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	2 / 47 (4.26%) 2	0 / 2 (0.00%) 0

Rash			
subjects affected / exposed	7 / 38 (18.42%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	7	2	0
Rash maculo-papular			
subjects affected / exposed	2 / 38 (5.26%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Swelling face			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Nail ridging			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Decubitus ulcer			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Dry skin			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Cold sweat			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Dermatitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Petechiae			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pruritus generalised			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin disorder			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	2 / 38 (5.26%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Nocturia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Acute kidney injury			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Haematuria			

subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Hydronephrosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urine flow decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Incontinence			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urinary hesitation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Urinary tract pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			

subjects affected / exposed	5 / 38 (13.16%)	5 / 47 (10.64%)	0 / 2 (0.00%)
occurrences (all)	5	5	0
Back pain			
subjects affected / exposed	4 / 38 (10.53%)	7 / 47 (14.89%)	0 / 2 (0.00%)
occurrences (all)	4	7	0
Muscle spasms			
subjects affected / exposed	1 / 38 (2.63%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	1	4	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 38 (0.00%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	0	4	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	3 / 38 (7.89%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	3	2	0
Myalgia			
subjects affected / exposed	2 / 38 (5.26%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Neck pain			
subjects affected / exposed	2 / 38 (5.26%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	2	4	0
Pain in extremity			
subjects affected / exposed	3 / 38 (7.89%)	4 / 47 (8.51%)	0 / 2 (0.00%)
occurrences (all)	3	4	0
Pain in jaw			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Groin pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Myopathy			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	1 / 38 (2.63%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Limb discomfort			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Soft tissue swelling			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	7 / 38 (18.42%)	1 / 47 (2.13%)	1 / 2 (50.00%)
occurrences (all)	7	1	1
Lung infection			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Oral candidiasis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Rhinitis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	5 / 47 (10.64%)	1 / 2 (50.00%)
occurrences (all)	1	5	1
Urinary tract infection			
subjects affected / exposed	4 / 38 (10.53%)	9 / 47 (19.15%)	0 / 2 (0.00%)
occurrences (all)	4	9	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Herpes zoster			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Localised infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Breast abscess			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Injection site cellulitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Chest wall abscess			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Escherichia sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infected skin ulcer infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pelvic infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Perichondritis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sepsis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Skin infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Catheter site infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Device related infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Enteritis infectious			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Mastitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Mastoiditis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Vaginal infection subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	11 / 38 (28.95%) 11	10 / 47 (21.28%) 10	0 / 2 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	3 / 47 (6.38%) 3	0 / 2 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	3 / 47 (6.38%) 3	0 / 2 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	2 / 47 (4.26%) 2	0 / 2 (0.00%) 0
Hypoalbuminaemia subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	1 / 47 (2.13%) 1	0 / 2 (0.00%) 0
Hypocalcaemia subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	2 / 47 (4.26%) 2	0 / 2 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	7 / 47 (14.89%) 7	0 / 2 (0.00%) 0
Hypomagnesaemia subjects affected / exposed occurrences (all)	4 / 38 (10.53%) 4	9 / 47 (19.15%) 9	0 / 2 (0.00%) 0
Hyponatraemia subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	3 / 47 (6.38%) 3	0 / 2 (0.00%) 0
Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 47 (0.00%) 0	0 / 2 (0.00%) 0
Hypovolaemia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Fluid retention			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 47 (4.26%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Hypoglycaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hyperalbuminaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Metabolic acidosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 47 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 38 (0.00%)	1 / 47 (2.13%)	0 / 2 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part C3: M6620 90 mg/m ² + Carboplatin AUC 5 mg·min/mL		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Non-small cell lung cancer			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tumour pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Metastases to central nervous system			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Brain neoplasm			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Metastases to peritoneum			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Flushing			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Hypertension			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Jugular vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vascular compression			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypotension			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
White coat hypertension			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lymphoedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Peripheral coldness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Embolism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Subclavian vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Superior vena cava occlusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Thrombophlebitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vein disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	0		
Chills			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	5 / 13 (38.46%)		
occurrences (all)	5		
Influenza like illness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injection site reaction			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Malaise			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Face oedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infusion site extravasation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infusion site reaction			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infusion site erythema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Axillary pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site rash			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site related reaction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Device occlusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypothermia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infusion site discomfort			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infusion site rash			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injection site phlebitis			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Mucosal inflammation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site pruritus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infusion site pruritus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site bruise			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site induration			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site inflammation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Extravasation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injection site mass			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injection site pruritus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Localised oedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Thirst			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Drug hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Prostatism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Testicular pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Testicular swelling			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Breast pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Menstruation irregular			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Metrorrhagia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pelvic pain			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Epistaxis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haemoptysis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Hypoxia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Laryngeal oedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pleuritic pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dyspnoea exertional			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Atelectasis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dysphonia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hiccups			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nasal ulcer			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sputum increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rales			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Respiratory failure			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Insomnia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Depressed mood			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hallucination			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Adjustment disorder with depressed mood			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dissociation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Blood bilirubin increased			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Blood creatinine increased			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Platelet count decreased			

subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Weight decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Platelet count increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Transaminases increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood calcium decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
White blood cell count increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bacterial test positive			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood calcium increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Blood magnesium decreased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Blood phosphorus decreased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Blood sodium decreased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Blood urea increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Blood uric acid increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Body temperature increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Eastern Cooperative Oncology Group performance status worsened subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Neutrophil count increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Fibrin D dimer increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Prothrombin time prolonged subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Respiratory rate increased			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Weight increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood Chloride Decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood albumin decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood cholesterol increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Amylase increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood pressure decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Glomerular filtration rate increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Troponin increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Infusion related reaction			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Allergic transfusion reaction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Animal bite			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Skin abrasion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Procedural headache			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Procedural pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Spinal fracture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Sinus bradycardia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Extrasystoles			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Left ventricular hypertrophy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pericardial effusion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Atrial fibrillation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ventricular arrhythmia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Balance disorder			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Dysgeusia			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	4 / 13 (30.77%)		
occurrences (all)	4		
Neuropathy peripheral			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Neuralgia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Poor quality sleep			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Post herpetic neuralgia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Neurotoxicity			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Serotonin syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Parosmia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sciatica			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vocal cord paralysis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Depressed level of consciousness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hemiparesis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Aphasia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Brain oedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hemiparaesthesia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hyperaesthesia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Memory impairment			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Migraine			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Restless legs syndrome			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sinus headache			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 13 (46.15%)		
occurrences (all)	6		
Leukopenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Thrombocytopenia			
subjects affected / exposed	6 / 13 (46.15%)		
occurrences (all)	6		
Febrile neutropenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Thrombocytosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Iron deficiency anameia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Leukocytosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Pancytopenia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Ear and labyrinth disorders			
Deafness subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Ear discomfort subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1		
Hyperacusis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Tinnitus subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
External ear inflammation subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Ear pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Middle ear inflammation subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Hearing impaired			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypoacusis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Neurosensory hypoacusis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Lacrimation increased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Photopsia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Periorbital oedema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye irritation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Eyelid edema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Photophobia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Diplopia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eye haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Foreign body sensation in eyes			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	4 / 13 (30.77%)		
occurrences (all)	4		
Diarrhoea			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Dyspepsia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Haemorrhoids			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	4 / 13 (30.77%)		
occurrences (all)	4		
Stomatitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	4 / 13 (30.77%)		
occurrences (all)	4		
Abdominal distension			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haematochezia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oral disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Paraesthesia oral			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rectal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Retching			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal discomfort			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oral pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Ascites			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Faeces discoloured			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gingival bleeding			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Odynophagia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Salivary hypersecretion			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Small intestine obstruction			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Abdominal pain lower			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Eructation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gingival pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gingival swelling			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oesophageal obstruction			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Oral dysaesthesia			
alternative dictionary used: MedDRA 18,22.1&21			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tongue ulceration			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Hepatomegaly			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Portal vein thrombosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Rash maculo-papular			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Swelling face			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nail ridging			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rash erythematous			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Decubitus ulcer			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dermatitis acneiform			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Dry skin			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cold sweat			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Petechiae			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pruritus generalised			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Skin disorder			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Skin ulcer			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Dysuria			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Nocturia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Pollakiuria			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Acute kidney injury			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Proteinuria			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hydronephrosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Chronic kidney disease			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Renal impairment			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Urine flow decreased			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Incontinence			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Micturition urgency			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Urinary hesitation			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Urinary incontinence			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Urinary tract pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Muscle spasms			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Musculoskeletal discomfort			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Musculoskeletal pain			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Myalgia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pain in extremity			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pain in jaw			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bone pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Myopathy			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pathological fracture			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Flank pain			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Muscular weakness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Limb discomfort			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Soft tissue swelling			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		

Lower respiratory tract infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Lung infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Oral candidiasis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Pneumonia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1		
Rhinitis subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 3		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1		
Conjunctivitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Herpes zoster subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Localised infection subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		
Oral herpes subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0		

Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Tooth infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Breast abscess			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Injection site cellulitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Chest wall abscess			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Escherichia sepsis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Genital candidiasis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Infected skin ulcer infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Oesophageal candidiasis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Pelvic infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Perichondritis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Sepsis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Bacterial infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Catheter site infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Clostridium difficile infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Device related infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Enteritis infectious			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

Influenza			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Mastitis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Mastoiditis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Vaginal infection			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 13 (30.77%)		
occurrences (all)	4		
Dehydration			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hyperkalaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Hypokalaemia			

subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Hypomagnesaemia			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hyperuricaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypovolaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Iron deficiency			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Fluid retention			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hypoglycaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Hyperalbuminaemia			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Metabolic acidosis			
subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 13 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 August 2013	<ul style="list-style-type: none">• To change cycle length from 28 to 21 days to align with standard chemotherapy cycle duration• To revise the definition of DLT• To add survival follow-up assessment for all subjects• Part A: To add cisplatin to the gemcitabine dose escalation after the initial gemcitabine escalation in order to determine the appropriate doses of M6620, cisplatin, and gemcitabine for Part C1• Part B: To add a cisplatin-only escalation in order to determine the appropriate doses of M6620 and cisplatin for Part C2• Part C: To expand Part C to 3 parts (Part C1 in NSCLC, Part C2 in TNBC, and Part C3 in SCLC)
26 November 2013	<p>To revise the definition of DLT</p> <ul style="list-style-type: none">• Part C: To delete urinalysis on Days 3 and 9• Parts C1, C2, and C3: To reduce the number of PK samples• Part C2: To exclude any prior platinum therapy for breast cancer in any setting (EC2)
16 May 2014	<ul style="list-style-type: none">• To clarify the definition of refractory disease (Part C3)• To clarify stopping rules for subjects with progression disease (PD)• Part C3: To revise EC2 to exclude subjects who have not received at least 1 cycle instead of 2 cycles of prior platinum-based chemotherapy for SCLC• To allow preparation of gemcitabine and cisplatin per institutional practice• To update all timed assessments including PK and biomarkers to coincide with the actual end of infusion and allow for sample collections relative to the end of infusion• To update acceptable PK sampling windows• To update SAE reporting information
12 June 2014	<ul style="list-style-type: none">• To remove the restriction on subjects receiving treatment with medications that are mainly metabolized by CYP3A4 as M6620 is not a potent inhibitor or inducer of Cytochrome P450(CYP) 3A and the probability of M6620 impacting such concomitant medications is low (EC14)• Part C3: To exclude subjects who had not received at least 1 cycle (rather than 2 cycles) of prior platinum-based chemotherapy for SCLC
13 August 2014	<ul style="list-style-type: none">• To remove the restriction on treatment duration for subjects who appear to tolerate and respond to treatment for future subjects who may have potential clinical benefit from extended therapy• To expand the pretreatment window for safety laboratory assessments to 3 days before dosing• To allow Cycle 1 Day 21 assessments to be performed on Cycle 2 Day 1
08 December 2014	<ul style="list-style-type: none">• To modify language to allow escalation of chemotherapy doses prior to escalation of M6620 to 200 mg/m² if exposures to M6620 exceed the predicted efficacious exposures at lower doses• To prevent pruritus by adding a rationale for management of potential infusion reactions, providing additional guidance for prevention, extending duration of M6620 infusion beyond 60 minutes, and updating the dilution volume for total doses of M6620 over 400 mg• Part C: To clarify that subjects who had received any prior platinum for squamous NSCLC except in the adjuvant or neoadjuvant settings are excluded
07 April 2015	<ul style="list-style-type: none">• To revise the definition of DLT to exclude transient Grade 3 elevations in liver function tests (LFTs)

10 June 2015	<ul style="list-style-type: none"> • To revise the definition of DLT to exclude any grade of acute hypersensitivity reaction or the need to interrupt or discontinue treatment in the event of acute hypersensitivity • Part C: To exclude subjects receiving treatment with ototoxic or nephrotoxic medications that could not be discontinued ≥ 7 days before the first dose of study drug and for the duration of the study • Parts C1 and C2: To allow subjects who discontinue for reasons other than PD, who are nonevaluable for efficacy, or who discontinue due to PD before completing Cycle 1 to be replaced • Part C1: To redesign Part C1 to evaluate safety and efficacy of M6620 in combination with gemcitabine in approximately 30 subjects with advanced NSCLC who have received previous chemotherapy • Part C2: To redesign Part C2 to evaluate safety and efficacy of M6620 in combination with cisplatin in approximately 50 subjects with advanced TNBC • Part C3: To delete Part C3, which aimed to evaluate safety and tolerability of M6620 in combination with cisplatin and etoposide in subjects with relapsed or refractory SCLC
14 December 2015	<ul style="list-style-type: none"> • Part C1: To remove Prescreening • Part C2: To remove the requirement for ≥ 30 subjects to be androgen receptor (AR) negative
16 February 2016	<ul style="list-style-type: none"> • To clarify that MRI or bone scans may be used as an alternative to computed tomography (CT) scans for disease assessment but that the same technique should be used for assessment of response in an individual subject throughout the study • To exclude subjects diagnosed with Li-Fraumeni Syndrome or ataxia telangiectasia (EC 12) • Parts C1 and C2: To add starting doses for M6620/gemcitabine and M6620/cisplatin in Parts C1 and C2, respectively • Part C1: To allow enrollment of subject who had received an additional line of nonplatinum-based chemotherapy and those who had received prior gemcitabine for the treatment of non-small cell lung cancer (NSCLC) within 6 rather than 12 months (EC2) • Part C1: To enroll 10 subject without TP53 mutation or without ATM loss of expression and to remove the requirement for eligible subject to have documented radiologic progression • Part C2: To exclude the following subjects (EC2): Those who had received any prior platinum therapy for breast cancer within 6 months (rather than 2 years) of Screening; Those who had relapsed within 3 (rather than 12) months after completion of prior adjuvant or neoadjuvant chemotherapy; Those who had received any prior chemotherapy in the metastatic setting except for either a taxane or an anthracycline and 1 other nonplatinum-based chemotherapy • Part C2: To allow escalation of the dose of M6620 from 140 mg/m² to 210 mg/m² with 75 mg/m² cisplatin if initial doses of M6620 and cisplatin were tolerated in the first 5 of 6 subjects for 2 cycles • Part C3: To add a new Part C3, to evaluate the safety and efficacy of M6620 in combination with carboplatin in approximately 25 subjects with platinum-resistant advanced SCLC • Parts C1 and C2: Cycle 1 Day 9 PK sample removed
21 August 2017	<ul style="list-style-type: none"> • To remove the 5 mg/mL formulation of M6620
25 January 2018	<ul style="list-style-type: none"> • To add Part B2

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

